IANZ

specific criteria
for accreditation

Ministry for Primary Industries

Recognised Laboratory Programme

12

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1   Introduction

International Accreditation New Zealand (IANZ) Specific Criteria amplify or particularise the IANZ general accreditation criteria, for specific fields of technology or for specific types of business activity.

This document must be read together with current issues of the IANZ general criteria for accreditation ISO/IEC 17025: *General requirements for the competence of testing and calibration laboratories*, and *Procedures and Conditions of Accreditation*, the latter document describing the organisation and operation of the IANZ Accreditation Programmes.

The Specific Criteria provides information on classes of test, staff, accommodation, equipment and other aspects of good laboratory management practice considered to be a minimum standard for accredited laboratories.

A list of Specific Criteria published to date is available here or from IANZ on request.

With the introduction of the Ministry for Primary Industries (MPI) Recognised Laboratory Programme (RLP) in 2015, laboratories accredited under the existing Dairy Testing, Laboratory Approval Scheme (LAS) and Export Laboratory (ELP) Programmes were required to undergo assessment and were subsequently accredited under the new MPI RLP.

One of the features of the MPI RLP is that accreditation is restricted only to those tests of regulatory significance and as set out in the MPI Consolidated Lists of Tests for Animal Products (CLT). Laboratories requesting accreditation for testing not included in the CLT will need to seek accreditation under the IANZ Chemical Testing and/or Biological Testing laboratory accreditation programmes.

2   Scope

This Specific Criteria sets out the specific requirements a MPI Recognised Laboratory has to meet in addition to the general requirements of ISO/IEC 17025, if it is to be accredited by IANZ.

Every testing laboratory seeking to be a Recognised Agency under the Animal Products Act 1999 (the Act) must be accredited by IANZ as meeting the requirements of ISO/IEC 17025. Laboratories need to be accredited in order to test materials (meat, seafood, dairy products, honey, etc.) for export to meet importing country requirements. However, under the RLP requirements, research or reference laboratories whose functions include calibration, quality assurance and specific testing parameters, and where urgent circumstances arise that require the laboratory to carry out certain tests, the laboratory may be recognised by MPI as a RLP testing laboratory without the need to be accredited.

Laboratories seeking accreditation under the RLP must therefore comply with the MPI Animal Products Notice: Specifications for Laboratories in addition to ISO/IEC 17025.

Copies of the MPI documents below need to be held or readily available in the laboratory as the requirements of these documents form part of the management system. These can be down loaded from www.foodsafety.govt.nz/industry/general/labs-recognised-persons-agencies/new-lab-specifications-notice.htm

- Animal Products Notice: Specifications for Laboratories
- Consolidated List of Tests for Animal Products.

Accreditation under this programme is therefore restricted to only those laboratories which are required to be recognised by the MPI in accordance with the Notice.

3 Definitions and Acronyms

Uncertainty and calibration
Definitions of these terms and other terms relating to measurements are contained in *International Vocabulary of Basic and General Terms in Metrology* (VIM) (see references).

MPI
Ministry for Primary Industries

RLP
Recognised Laboratory Programme

CLT
Consolidated Lists of Tests

NMD
National Microbiological Database

4 Scopes of Accreditation

IANZ accreditation does not constitute a blanket approval of all of a laboratory's activities, accreditation only extends to those activities covered by the CLT.

The IANZ scopes of accreditation under the MPI RLP mirror that of the MPI CLT. Additional (accredited) testing not included in the CLT is not permitted. IANZ accreditation will only be granted, and published in the scope of accreditation, for those tests on the CLT that the laboratory has demonstrated its capability to perform competently.

Current issues of the IANZ Schedules to the Certificates of Accreditation (Scopes of Accreditation) can be viewed via the IANZ Directory at www.ianz.govt.nz.

5 Laboratory Accommodation and Safety

5.1 General requirements

Accommodation requirements for RLP testing vary widely depending on the nature of the testing involved.

Irrespective of where tests and measurements are performed, there must be adequate space and storage facilities for carrying out the tests, recording of test data, report preparation, etc. and storage facilities for samples including retained samples.

Formal laboratory areas must have good lighting, adequate bench space, freedom from excessive dust and fumes, freedom from unwanted vibration and acoustic noise and, for some tests, control of temperature and humidity, or light levels. For the majority of laboratories, air conditioning is considered essential. The extent to which these environmental factors apply will vary according to the type and precision of the testing. Factors that may need to be considered include but are not necessarily restricted to:

a) Isolation from sources of stray electric and magnetic fields, mechanical vibration and shock likely to have a detrimental effect on sensitive instruments (e.g. high accuracy balances)

b) Adequate ventilation when fumes are created during the testing procedure. This includes adequate ventilation during autoclave activities

c) Suitable equipment and areas for the preparation of test samples

d) Areas with subdued lighting may be needed for the performance of test procedures such as vitamin analysis, etc.

Storage facilities must be sufficient to allow for the retention and, where relevant, segregation of samples for designated periods and provide conditions that maintain sample integrity. Refrigerators or freezers must have adequate capacity when samples require refrigeration before or after testing.

5.2   Microbiology Laboratories

The internal layout should generally provide for sample receipt, washing-up and sterilisation, media preparation, general testing and incubation areas. A distinct space, if not a separate room, should be used for microbiological testing in a laboratory complex. Where specialist testing e.g. sterility, pathogens or molecular biology (PCR) is involved, this would normally be mandatory. The laboratory layout should be designed to minimize potential contamination and to ensure protection of personnel and prevention of contamination of samples.

The design of workbenches, cupboards, shelves and the finish of all surfaces (i.e. benches, floors, ceilings, walls and windows) must facilitate cleaning and sterilisation. Walls, floors, ceilings and work surfaces shall be non-absorbent and easy to clean and disinfect. Wooden surfaces of fixtures and fittings shall be adequately sealed. Measures should be taken to avoid accumulation of dust (e.g. sufficient storage space, minimal paperwork, documented cleaning programme for laboratory areas, fixtures and equipment).

High standards of housekeeping are essential and routine housekeeping procedures should be documented. Since all analyses are susceptible to contamination, the laboratory should document and implement procedures and precautions to be taken to prevent contamination from the air, the personnel, aerosols and dust. Instructions must be available for procedures such as washing glassware, generating distilled, deionized or reagent water, sterilisation and wiping down of bench tops, etc.

The laboratory environment, where relevant, shall be microbiologically monitored for trends and anomalies and records shall be kept. Laboratories should devise appropriate programmes of monitoring with respect to the type of testing being carried out. As a minimum, monitoring should be of airborne contamination e.g. exposure plates. Swabbing of critical surfaces such as sampling and testing benches, utensils, balances, stomachers, etc. are also recommended, and in pathogen testing laboratories this would be considered essential. Acceptable background counts shall be assigned and there shall be a documented procedure for dealing with situations in which these limits are exceeded.

Where necessary, appropriate pest and vermin control measures are expected to be in place.

The suitability of the accommodation will be judged on whether it is likely to adversely affect the samples, equipment, staff performance or final test results.

References such as AS/NZS 2243, or an appropriate Code of Practice registered with the Department of Labour (OSH) should be consulted when Laboratory Safety Procedures are being prepared and implemented.

6   Laboratory Equipment Management and Calibration

Management and calibration requirements for equipment are given in ISO/IEC 17025. Guidelines on calibration intervals for laboratory equipment items are given in Appendix 2.

6.1   Measurement Traceability

Traceability of a measurement result is ensured when the result can be related to a stated reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty (see references 5, 20).

The IANZ policy on traceability of measurement is set out in the IANZ Technical Policy No.1: *Traceability of Measurement*. All IANZ accredited testing laboratories are required to maintain conformity with this policy.

The calibration certificates issued by accredited laboratories must be endorsed in accordance with the requirements of the accreditation bodies concerned. This constitutes proof of traceability.

6.1.1 Traceability of Chemical and/or Biological Substances and Biological Organisms

The SI unit for the amount of substance (e.g. for chemical testing) is the mole. To fully realise the mole as a base unit, it is necessary to specify not only the amount but also the specific substance referred to. For microbiological testing where the "amount of substance" is the organism(s) being measured, the same principles apply i.e. both the base unit of the organism has to be realised along with its unique identity. This can provide considerable practical difficulties and, therefore, alternative approaches to establishing traceability in chemical and biological measurement need to be applied.

The fundamental motivation for establishing and demonstrating traceability in chemical and biological measurement is to ensure (or at least improve) comparability of results from different laboratories across both space and time. In order for chemical and/or biological measurements to be comparable, there are several critically important components of traceability.

The first is the chemical analyte or biological entity/organism to be measured (the "measurand"), which must be clearly and unambiguously defined i.e. to ensure that the results being compared are of the same substance or biological entity. Often in chemical measurement and most often in biological measurement the measurand is defined by the methods of measurement used e.g. fat content, moisture by gravimetry, solubility, aerobic plate count, organisms to species level only, sterility testing, etc. Such methods that define the measurand are often called empirical methods.

The next component in chemical and biological traceability is the defined measurement or test method used to provide an estimate of the measurand quantity. The development of a method leads to:

(a) A set of instructions for the conduct of the test

(b) A set of test conditions detailing the parameters that must be kept fixed or stable e.g. the composition and purity of an extraction solvent, time and temperature of drying/ashing, the wavelength chosen for a spectrophotometric absorbance, growth media, incubation times and temperatures, incubation environmental conditions (such as anaerobic conditions), etc. Defined test conditions and adherence to these conditions is especially important in empirical methods

(c) A method equation from which the result or quantity of the measurand is calculated using the values of the other measured parameters.

Validation of this test method plays a key role in establishing traceability as it determines whether the assumptions made in setting the method conditions are valid. Validation determines the relative importance of these conditions and rigour to which they need to be monitored and controlled.

Where validation shows that a particular condition is critical to the validity of the test result, then the monitoring and control requirements of this condition are part of the defined traceability of the measurand. For example, where incubation or drying times and temperatures are critical to the outcome of the test, these parameters will need to be measured and these measurements themselves need to be traceable.

In essence, therefore, a chemical or biological measurement can be considered traceable when:

(a) The defined test method is followed as prescribed, and

(b) Each of the measured parameters in the method conditions are traceable to appropriate standards, and

(c) Each of the measured parameters in the method equation are also traceable to appropriate standards.

The traceability of each of these measured parameters is achieved through calibration.

Where these parameters are defined physical measurements – and this is typically the case for the test method conditions in (b) above, e.g. time and temperature previously mentioned, and mass (of the sample tested for example) - the traceability chains are well established and requirements for these are given in Section 6.2 below.

Often, however, and especially for the parameters associated with the method equation in (c), the parameter is a visual or instrument response and the means of establishing traceability of these are discussed as follows.

6.1.2   Chemical Testing

Often in chemical testing, the parameter is an instrument response (peak height/area, absorbance, etc.) compared with a calibration from a "known" amount of substance – a reference standard, which may be a pure analytical standard or a matrix reference material. The mechanisms to ensure traceability of such reference material are, in most areas, not well developed. It is also recognised that availability of reference material complying with the generally accepted mechanisms to ensure traceability is limited.

Nevertheless, chemical testing laboratories are expected to source their reference materials (RMs) (which include analytical standards) from the following possible sources (generally in decreasing order of preference) where availability permits:

(a)   Certified Reference Materials (CRMs) from national measurement institutes which provide these e.g. National Measurement Institute (NMI) in Australia, NIST (USA), BCR (Europe)

(b)   CRMs from accredited (to ISO 17034) reference material producers

(c)   CRMs and RMs from well-established and reputable reference material producers

(d)   Reputable chemical supply houses (particularly for pure analytical standards)

(e)   Customer supplied reference standards, preferably with certification

(f)   In-house produced reference standards.

For materials without formal evidence of traceability (and associated uncertainty information), it remains the laboratories' responsibility to demonstrate the materials are fit for their intended purpose.

CRMs are defined as a reference material that is characterised by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value(s) of the specified property(ies), its (their) uncertainty(ies), and a statement of metrological traceability.

A RM is a material sufficiently homogenous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

In addition, for empirical methods, traceability relies on the laboratory complying in full with the method as published (as this defines the measurand). Other methods to determine this defined measurand are possible but must be validated or "calibrated" against the primary reference method defining the measurand e.g. measurands such as fat, protein or moisture in foods by near-infrared reflectance spectroscopy, need to have a clearly established relationship with results achieved by the reference method.

6.1.3   Microbiological Testing

In microbiology, the parameter is usually a visual or instrument response (such as typical colonies on a plate of medium, a biochemical or immunoassay response, etc.). These often are or can be compared with a "known" response of the pure organism or biochemical.

6.1.3.1 Biochemical Traceability

Particularly where a reference standard is biochemical or immunological in nature, the mechanisms to ensure traceability of such reference material are not well developed. It is also recognised that availability of reference material complying with the generally accepted mechanisms to ensure traceability is limited.

Biological testing laboratories are expected to source their reference materials (particularly when biochemical or immunological in nature) from the following possible sources (generally in decreasing order of preference) where availability permits:

(a)   Reference standards from national measurement institutes, from accredited (to ISO 17034) reference material producers or from reputable reference material producers

(b)   Reputable chemical supply houses (particularly kit manufacturers and for pure biochemical standards or reagents)

(c)   Customer supplied reference standards, preferably with certification

(d)   In-house produced reference standards.

6.1.3.2   Biological Organism Traceability

As discussed in the first paragraph of Section 6.1, the traceability of these pure biological entities to an accepted universal standard such as an SI unit involves realisation of both identity and quantity.

(a)   Traceability of Identity

Microbiological testing laboratories have access to international or national culture collections to source their reference strains of organisms, including bacteria, viruses and the like. RLP testing laboratories are expected to source their reference materials or organisms from the following possible sources (generally in decreasing order of preference) where availability permits:

(i)   For microbiological laboratories, directly from national or international type culture collections e.g. The New Zealand Reference Culture Collection (ESR Kenepuru Science Centre), ATCC (USA), NCTC (UK)

(ii)   Reference standards (particularly when biochemical or immunological in nature) from national measurement institutes, from accredited (to ISO 17034) reference material producers or from reputable reference material producers

(iii)   Reputable chemical supply houses (particularly kit manufacturers and for pure biochemical standards or reagents)

(iv)   Customer supplied reference standards/organisms, preferably with certification

(v)   In-house produced reference standards/organisms.

For materials without formal evidence of traceability it remains the laboratory's responsibility to demonstrate the materials/organisms are fit for their intended purpose.

(b)   Traceability of Quantity

Any test method involving the measurement of parameters associated with a living biological organism will, by its very nature be empirical in that the result obtained will be dependent on the defined method conditions and how the organism of interest is treated. Comparability of results (and particularly quantitative measurements), and thus measurement traceability, is entirely dependent on laboratories complying in full with the detail of the defined method as published.

While other methods to determine **the defined measurand** are possible, these must be validated or 'calibrated' against the primary reference method defining the measurand e.g. when changing culture media or incubation time and/or temperatures, when adopting non-culture methodology for traditional culture methods, etc.

6.1.4   Traceability of Physical Measurements

Traceability requires that there is a chain of equipment whose calibrations to known levels of uncertainty are traceable from one item to the next and eventually to a national standard of measurement. The concept of traceability also includes the competence of all the people involved, the fitness of each measurement environment, the suitability of the methods used and all other aspects of the quality management systems involved at each step in the chain of measurements.

Traceability must be established for all critical* measurement and calibration equipment either:

(a)   Directly to the national standards laboratory (Measurement Standards Laboratory) or another such national body (e.g. National Measurement - Australia) acceptable to the Measurement Standards Laboratory, or

(b)   From a third party accredited calibration laboratory that is accredited by IANZ or an accreditation body with which IANZ has a mutual recognition agreement/arrangement.

The calibration certificates issued by accredited calibration laboratories must be endorsed in accordance with the requirements of the accreditation bodies concerned. This constitutes proof of traceability to national standards.

Endorsement to ISO 9000 standard is not considered acceptable.

*Critical measurements/calibrations are those that will significantly affect the validity of the reported results.

6.2   Calibration

Laboratory equipment and its suitability ranks on a level equal to the competence of the staff using it. An accredited laboratory will be expected to possess and maintain, under a documented management system, all equipment necessary to carry out the tests requested for inclusion in the scope of accreditation.

Guidelines on calibration requirements and re-calibration intervals for specific items of equipment are detailed in Appendix 2. The guidelines set out maximum periods of use before equipment must be re-calibrated. These periods have been established by accepted industry practice and, in most instances, are the maximum permitted re-calibration intervals as laid down by international convention. Where a test method or operating environment requires a more stringent recalibration period than given here, the more frequent calibration will apply.

IANZ may accept reduced or extended calibration intervals based on factors such as history of stability, accuracy required and ability of staff to perform regular checks. It is the responsibility of the laboratory to provide clear evidence that its calibration and maintenance system will ensure that confidence in the equipment can be maintained.

Precision balances that are being used to their full readability i.e. to the last place showing, will also require full re-calibration by an appropriate calibration authority i.e. external calibration, if they are moved to a different location. Balances being used for less than their accuracy limit may be re-validated using appropriate QC methods i.e. single point and repeatability checks with standard check masses.

Records of calibrations carried out in-house must confirm traceability of measurement (see Section 6.1 above). This is normally achieved by the record specifically identifying the reference item used, the date and the person performing the work using the documented procedure.

Calibration of an instrument as a whole rather than individual components of it is sometimes necessary, often as part of the test run. Chromatographic systems are examples.

6.2.1   Measurement Uncertainty in Calibration

ISO/IEC 17025 requires testing laboratories that perform their own calibrations to have and apply a procedure to estimate the uncertainty of measurement in all 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 or proper performance of the test and which are approaching the performance specification of the equipment item. Examples would include the calibration of analytical balances, thermometers requiring a high level of (relative) accuracy; and the like.

RLP testing laboratories are recommended to have these items calibrated by an accredited external agency (see Section 6.2 above). If RLP testing laboratories wish to calibrate these items themselves, a full measurement uncertainty budget is expected to be estimated. This would normally be expected to be estimated in accordance with the *Guide to the Expression of Uncertainty of Measurement* (Reference 7). The IANZ *Specific Criteria for Accreditation in Metrology and Calibration (AS LAB C5)* should be consulted for further information.

Uncertainty of measurement estimations for periodic checks conducted in-house on calibrated equipment i.e. conducted between full calibrations, are not required.

7   Laboratory Staff

An accredited laboratory must have at least one staff member who is competent in the testing being undertaken.

The qualification and appointment of Key Technical Personnel is an internal process in the laboratory under the responsibility of the laboratory management.

The expected roles and qualifications of a Key Technical Person are given in Appendix 1.

The following requirements in regard to Key Technical Personnel are reviewed as part of the assessment process:

(a)   Appointment of Key Technical Personnel will be the responsibility of a designated senior laboratory officer who is a member of the laboratory's senior management team. Laboratories are required to have a documented person/position specification for Key Technical Persons and a documented and formal process for their qualification and appointment.

(b)   The laboratory will maintain a list of current Key Technical Personnel, including the technical scope of their areas of responsibility. This list may be included in the laboratory's quality manual or as a separate document, but must be maintained up-to-date at all times. The technical scope for each individual is to be described with reference to and in the terms of the MPI CLT (and associated IANZ scope of accreditation). There must be at least Key Technical Person appointed for each test in the laboratory's scope of accreditation.

(c)   The list of Key Technical Personnel and their individual scope of responsibility must be notified to IANZ who will maintain this listing for each accreditation. IANZ will request this information, in addition to the completed RLP KTP Test Selection Appointment Form, in the Application for Accreditation or Reassessment documentation provided prior to the three yearly reassessment and will also review it with laboratories during their assessment.

(d)   Changes to Key Technical Personnel listings (including individuals who have left the laboratory, new Key Technical Person appointments or changes in the technical scope of responsibility) made between annual on-site assessments must also be notified to IANZ. This is the responsibility of the laboratory's Authorised Representative.

(e)   In addition to the laboratory's usual training records, each Key Technical Person is required to have a brief CV-type summary of qualifications and experience. This CV information will be requested for each appointed Key Technical Person in the Application for Accreditation/Reassessment documentation described above. This information is also expected to be provided to IANZ when new Key Technical Personnel are appointed and notified to IANZ outside of annual assessments.

(f)   Where a laboratory loses the sole Key Technical Person for all or part of their scope of accreditation and no new appointment is made by the laboratory management, then the laboratory's accreditation (or part thereof) will be suspended until such time as a new appointment is notified to IANZ. Where new Key Technical Personnel appointments are made outside of routine reassessments, and particularly when a new appointment is the sole Key Technical 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 integrity of the laboratory's tests results will continue to be maintained.

(g)   All IANZ-endorsed test reports issued by an accredited laboratory must be signed or authorised by a Key Technical Person nominated by the laboratory. See Section 10.2.1.

IANZ assessment teams may not interview all appointed Key Technical Personnel. The Key Technical Personnel will still generally be expected to be the escorts for IANZ assessment teams during the course of an on-site assessment, with any of the appointed individuals being selected for the particular part of the scope of accreditation being assessed. The team may also choose to interview other levels of technical staff.

In the case where a particular Key Technical Person is not able to demonstrate to the assessment team that the laboratory is continuing to maintain the requirements for accreditation, it is not the individual who is considered to have "passed" or "failed" but rather the laboratory as a whole on the grounds of inadequate,

continuous technical supervision, and it may be that the affected part of the scope of accreditation is suspended.

8 Laboratory Test Methods

Section 4 above sets out the test method requirements for laboratories accredited under the RLP Testing Laboratory Accreditation Programme. Methods selected via the CLT may either be a mandated test method reference, or as per the scope of accreditation. Only those determinands listed under the CLT may be sought for accreditation in the RLP accreditation programme.

For laboratories testing meat samples for export testing, the NMD requirements for sampling and testing also apply.

8.1 Standard Methods

Where standard methods are prescribed and followed (e.g. those required by MPI CLT) the laboratory is expected to maintain current versions of the standard methods (reference texts) and up-date laboratory bench methods in accordance with these.

Although full validation is not required, a laboratory must verify that it can properly operate the method and can demonstrate (where specified) the limits of detection, selectivity, repeatability and reproducibility can be obtained with records of the verification retained.

8.2 Kits

Commercial test systems (kits) will require further validation if the laboratory is unable to source the validation data from manufacturers with a recognised quality assurance system, reputable validation based on collaborative testing, e.g. AOAC Official Methods and associated JAOAC publications or independently reviewed methods such as AOAC Performance Tested Methods.

8.3 In-house methods

In-house methods could include but not be restricted to:

(a)   Methods developed in the laboratory

(b)   Methods developed by a customer

(c)   Methods developed for an industry group

(d)   Modified standard test methods, especially methods being applied to different matrices or analyte concentrations that from those for which the method is validated

(e)   Methods from scientific publications, but which have not been validated.

Validation procedures shall involve, as appropriate, the aspects referred to in ISO/IEC 17025. Appendix 3 provides some guidelines for method validation in chemical and microbiological testing.

Standard test methods should be used whenever possible in order to ensure inter-laboratory reproducibility of test results. Laboratories are discouraged from seeking accreditation for test methods that depart from recognised published standards. If however, accreditation of an in-house test method is required, the following information must be provided:

(a) A copy of the fully documented test method

(b) Details of the origin of the in-house test method

(c) Details of the reason for its development and application e.g. the specification against which the RLP product/produce is being tested

(d) The results of comparative tests with standard methods (if possible) and/or with other laboratories

(e) Full details of test method validation as described in ISO/IEC 17025.

Once a laboratory is accredited for a specific test method, the detailed procedures of that method must be adhered to at all times.

9 Measurement Uncertainty

9.1 Measurement Uncertainty

It is important for testing laboratories to understand the concept of measurement uncertainty. Laboratory management should be aware of the effect that their own measurement uncertainty will have on test results produced in their laboratory. ISO/IEC 17025 requires testing laboratories to estimate their measurement uncertainty in the testing they conduct.

Readers are encouraged to familiarise themselves with current developments through sources such as those detailed in the References (e.g. 6, 7, 8, 9, 10, 13, 19). It is noted that measurement uncertainty is closely related to the concept of traceability and, in metrological terms, it relates to the uncertainty inherent in the chain of comparisons from the laboratory's result to the SI or other defined reference.

The following details the current requirements for laboratories accredited under the RLP Programme:

(a) Laboratories need to make a formal estimate of measurement uncertainty for all tests in the scope of accreditation that provide numerical results. Where results of tests are not numerical or are not based on numerical data e.g. detected/not detected, pass/fail, positive/negative, or based on visual, tactile or other qualitative examinations, estimates of uncertainty are not required.

(b) Where an estimate of measurement uncertainty is required, laboratories need to document their procedures and processes on how this is to be done.

There are various published approaches to the estimation of uncertainty in testing. ISO/IEC 17025 does not specify any particular approach. All approaches which give a reasonable estimate and are considered valid within the chemical and biological testing communities are equally acceptable and no one approach is favoured over others. For guidance, Appendix 4 sets out a possible approach which IANZ would recommend as being consistent with approaches internationally. This approach is not mandatory but alternative approaches would be expected to address the principles embodied within it. Laboratories are referred to the references quoted above for further information.

What is important is that laboratories document, with reference to published procedures, what their approach to estimating uncertainty in measurement will be. IANZ assessment teams will assess the suitability and rigour of these approaches during regular assessments, particularly full reassessment every third year.

(c) Once a documented procedure is established, the laboratory needs to implement a programme for applying this procedure to all relevant tests within the scope of accreditation.

The procedures in (b) above may require a redesign of current quality control programmes and data may need to be collected over a reasonable length of time in order to make a sufficiently rigorous assessment of measurement uncertainty. Laboratories will need to maintain records of each test or type of tests to demonstrate full implementation of the procedure required by (b) above.

9.1.1 Reporting Measurement Uncertainty

RLP recognised laboratories are not currently required to report their estimated measurement uncertainty on test reports as a matter of routine.

However, ISO/IEC 17025 requires reporting of measurement uncertainty when it is required for the correct application or interpretation of the test result. One such instance is where test results are used to determine if a sample conforms to a required numerical specification and where the specification limit falls within the limits of measurement uncertainty associated with the test result obtained.

9.2 Limits of Detection

For some RLP chemical testing, method detection limits will need to be determined i.e. where laboratories are performing analyses at low analyte levels such as in residue testing and low level micronutrient testing.

As with measurement uncertainty, there are various published methodologies for the determination of method detection limits. In general, these different methodologies are associated with either:

(a) The source of the published standard methods e.g. Codex, AOAC, etc., or

(b) The specific industry sector the laboratory is operating within and in which the results are used.

Where the determination of method detection limits is applicable, laboratories will need to have a documented procedure on how they determine their detection limits. The procedure should be consistent with the source of methodologies normally used (e.g. if published reference method details detection limit determination methodology, then the laboratory should adopt these recommended practices for method detection limit determination); or the conventions used within the industry sector.

In the absence of industry or test methodology conventions, there is an expectation that laboratories will determine method detection limits from a series of independent analyses of the analyte concerned in the matrix of interest at a level near the expected limit of detection. The method detection limit is calculated from the variation of results at this level and is not to be confused with a so-called instrument level of detection obtained from readings of a series of blanks.

In some cases, the sensitivity of the instrument is such that the lowest calibration standard is more than two orders of magnitude below the regulatory limit. In this situation, laboratories may sometimes set the limit of detection at the level of the lowest calibration standard, but this approach does require that the laboratory consider the manner in which they report low positive results below the artificially high limit of detection to ensure that reports are not misleading to the users.

10 Reports and Records

10.1 Test Records

An adequate test records system in accordance with the various clauses of ISO/IEC 17025 is essential.

Most laboratories have developed forms (proforma sheets) for all of their routine testing. These are generally the preferred option as their use prompts the recording of all the required information, maintains consistency and increases recording efficiency.

Test records may also be contained in personal or test specific workbooks. Where such workbooks are free text i.e. not bound proforma sheets, this type of records system is generally less efficient and requires a greater level of management to ensure that records are not lost. For these reasons, free text recording systems are now usually found only where a high level of non-routine testing is carried out, e.g. in research organisations.

Where a laboratory has implemented electronic records such as Microsoft Excel spreadsheets and Access databases, or has installed a Laboratory Information Management System (LIMS), then appropriate validation and document control needs to be in place.

10.2 Test Reports

ISO/IEC 17025 sets out the requirements for test reports issued by testing laboratories.

Test reports must give the customer all relevant information and every effort should be made to ensure that the test report is unambiguous. All information in a test report must be supported by the records pertaining to the test. All information required to be reported by the test specification must be included in the report. It is recognised that in many instances, particularly in the RLP manufacturing sector, regulatory requirements and industry accepted practice will determine the report format and content.

Laboratories must retain an exact copy of all reports issued. These copies must be retained securely and be readily available for the time specified in the laboratory's documented policies.

10.2.1 IANZ-Endorsed Test Reports

Accredited laboratories are permitted to include reference to their accreditation in the test reports they issue. The general rules governing the use of IANZ endorsements are detailed in the IANZ publication *Procedures and Conditions of Accreditation (AS 1)*.

For RLP testing laboratories, all test reports carrying the IANZ endorsement must be formally authorised by at least one of the laboratory's nominated Key Technical Personnel (see Section 7 and Appendix 1). This would normally be by a signature on the report itself (see also Section 10.2.2 below).

It is recognised that many of today's laboratories are multi-disciplinary in nature and, in some cases, very specialised within disciplines. Test reports pertaining to a particular sample or set of samples may include test results from several specialist areas and/or disciplines.

While the technical scope of nominated Key Technical Persons is expected to match their expertise in various specialist areas and/or disciplines, it may not be practical to expect a number of Key Technical Personnel to sign a test report to cover each of the results that may be reported therein. In these instances, it is acceptable that a multi-disciplinary test report is signed by only one of the laboratory's Key Technical Persons under the following conditions:

(a) The individual authorising the test report is responsible for ensuring all results which are outside their technical scope as a Key Technical Person (and that are included in the test report) have been authorised or released internally by a Key Technical Person (or delegated staff – see Appendix 1) with these tests in their technical scope

(b) There is a clear audit trail within the laboratory's system to demonstrate this.

10.2.1.1 Opinions and Interpretations

ISO/IEC 17025 allows for test reports to include statements of opinion and interpretation related to the test results. Under the RLP, it is the policy of IANZ that accreditation is not granted to laboratories for providing statements of opinion and interpretation of test results.

Except where an interpretation is clearly factual (e.g. a statement of compliance or otherwise with a specification), opinions and interpretations cannot be implied as being within the scope of the laboratory's accreditation on an IANZ-endorsed test report.

This does not preclude accredited laboratories from making such statements as an added value service to their customers. However, they should either be given in a (non-IANZ endorsed) separate document to the test report, or if included directly in IANZ-endorsed reports, a clear disclaimer made that the statements made are outside the laboratory's scope of accreditation.

10.2.2 Electronic Reporting

Traditionally, laboratories issued test reports in hard copy format with manuscript signatures (from Key Technical Personnel if the test report was IANZ-endorsed). The reporting requirements of ISO/IEC 17025 need to be applied whether the reports are provided to the customer in hard copy or electronic format. While it is difficult to specify in detail a set of requirements to address every eventuality (as laboratories will tend to develop electronic reporting systems to suit their own circumstances and those of their customers), the following is intended to provide guidance on common issues of concern.

10.2.2.1 Transmission of Reports

It is the responsibility of the issuing laboratory to ensure that what is transmitted electronically is what is received by the customer.

Email systems have proven to be robust in this regard, but laboratories need to consider whether customers will have the appropriate software and version to open attachments without corruption.

Laboratories should verify (at least initially and periodically thereafter is recommended) the integrity of the electronic link e.g. by asking the customer to supply a copy of what was received and comparing it with what was transmitted. It is also important that the laboratory and its customer agree as to which part of the

electronic transfer system they are responsible for and the laboratory must be able to demonstrate data integrity at the point the data comes under the control of the customer.

10.2.2.2 Security

Laboratories should avoid sending test reports in an electronic format that can be readily amended by the recipient. Examples would be in word processing or spreadsheet software. Where possible, reports should be in a read only format e.g. pdf files.

Where this is not possible e.g. the customer may wish to transfer the reported results file into a larger database, then laboratories are recommended to indicate these electronic reports have an interim status and are followed-up by a hard copy (or more secure) final report.

Laboratories must retain an exact copy of what was sent. This may be a hard copy or an electronic copy. These copies must be retained securely and be readily available for the time specified in the laboratory's documented policies.

10.2.2.3 Electronic Signatures

All reports (whether hard copy or electronic) must not be released to the customer until authorised by individuals with the authority to do so. For electronic reports, there must be a clear audit trail with a positive authorisation record to demonstrate this is the case. Where this is managed through password access levels in the laboratory's electronic system, appropriate procedures should be in place to prevent abuse of password access.

The electronic report should show the identity of the individual releasing the report (a nominated Key Technical Person in the case of IANZ-endorsed reports). The security of these signatures should be such as to prevent inadvertent use or abuse.

10.2.2.4 Report Format

ISO/IEC 17025 allows for simplified report formats for internal customers or in the case of written agreement from the customer. This is often the case for electronic reports. While the laboratory may be accredited for the testing, it is usual such reports would not normally carry the formal IANZ-endorsement.

IANZ-endorsed reports, whether electronic or not, would normally be expected to comply with the requirements (as appropriate) of ISO/IEC 17025.

11 Quality Control

It is essential that accredited RLP testing laboratories have developed, documented and implemented an appropriate quality control (QC) programme.

ISO/IEC 17025 suggests various quality control procedures that can be included in a laboratory's day-to-day activities and each laboratory is expected to implement the procedures most appropriate to their circumstances. Quality control data should be analysed and where it is found to be outside pre-defined action criteria, the defined actions shall be taken to correct the apparent problem and to prevent incorrect results from being reported.

It is important for laboratories to understand where tests can go wrong so that steps can be taken to either eliminate the potential error point or put in an appropriate QC step for alerting the operator when the test has gone wrong. Quality control in some form is possible with any test being performed. A disciplined approach is required for the development of a suitable QC plan and this approach should be applied on a test-by-test basis.

The quality control programme should be designed in such a way as to demonstrate that the on-going control of both the accuracy and precision of each test is being maintained.

Where tests are performed infrequently, the laboratory should carry out regular performance checks to demonstrate its continuing competence to perform them or have in place a system for demonstrating proficiency prior to performing the test on a customer sample.

11.1   Quality Control in Microbiology Laboratories

As discussed in Section 6, microbiological testing methods are for the most part empirical in nature. The result obtained (and its associated traceability) is dependent on adherence to the method used, including the method conditions specified. Short of revalidating the method conditions every time the test is conducted (e.g. by the quantitative assessment of the recovery of a reference organism from the sample matrix for each sample tested – see Appendix 3), laboratories need to implement a quality control programme that ensures the method conditions are adequately controlled. This control procedure will also ensure the method conditions (or parameters contributing to the measurement uncertainty – see Section 9 and Appendix 4) operate within defined parameters and, thus, have a predictable and consistent contribution to the uncertainty in the measurement results.

In essence, all possible inputs into the testing system need some level of quality control to ensure consistency to the quality of the results produced.

Many published method texts have chapters which detail such quality control programmes suited to their particular application (e.g. References 13, 14, 15, 16). The guidelines in this document are not intended as a replacement for these, but rather a summary of the key issues and as a resource for laboratories which do not have ready access to such texts.

Some of the key inputs common to most microbiological testing which need to be subject to such a quality control programme can be summarised as follows:

(a)   Personnel (Section 7 and Appendix 1)

(b)   Valid test methods (Section 8 and Appendix 3)

(c)   Laboratory accommodation and environment (Section 5)

(d)   Equipment and its calibration (Section 6 and Appendices 2 and 5)

(e)   The authenticity and maintenance of reference organisms to ensure their validity and viability (Appendix 6)

(f)   Consumables used in the conduct of the tests including media, reagents and diluents and their preparation (also Appendix 7)

(g)   Laboratory supplies and equipment having direct contact with the samples/organisms under test (Appendix 8).

This list is not necessarily exhaustive and additional quality control requirements may be required by method specifications, industry standards or general good practices. Similarly, the application of these particular requirements may not be necessary in all instances.

12   Proficiency Testing

The IANZ policy on participation in proficiency testing activities is set out in the IANZ Technical Policy No.2: *Participation in Proficiency Testing Activities.* All IANZ accredited testing laboratories are required to maintain conformity with this policy.

For RLP laboratories testing meat, meat products and seafood, Part 2 of the CLT also sets out the mandatory proficiency testing participation requirements for the microbiological testing of potable water, meat, poultry and seafood, and for the chemical testing of meat, tallow, fats, and potable water. These mandatory participation requirements also contain requirements for the management of out of specification rounds, with turnaround times for requesting additional samples and reporting timeframes that must be complied with.

13   References

1. ISO/IEC 17025 – *General requirements for the competence of testing and calibration laboratorie*s

2. Procedures and Conditions of Accreditation (AS 1), IANZ

3. MPI Animal Products: Specification for Laboratories

4. AS/NZS 2243 – *Safety in Laboratories*

5. BIPM - *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms* (VIM, 3rd edition); JCGM 200:2012
   (see http://www.bipm.org/en/publications/guides/)

6. Eurachem/CITAC Guide: *Traceability in Chemical Measurement – A guide to achieving comparable results in chemical measuremen*t, 2003
   (see https://www.eurachem.org/index.php/publications/guides)

7. BIPM - *Evaluation of measurement data — Guide to the expression of uncertainty in measurement* (GUM); JCGM 100:2008
   (see http://www.bipm.org/en/publications/guides/)

8. Eurachem - *Quantifying Uncertainty in Analytical Measurement*, 3rd Edition (2012)
   (see https://www.eurachem.org/index.php/publications/guides)

9. ISO 5725-1:1994 – Accuracy (trueness and precision) of Measurement Methods and Results

10. Asia Pacific Laboratory Accreditation Cooperation (APLAC) TC005: *Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing*
    (see https://www.aplac.org/index.php?id=89)

11. ISO/IEC 17043 – *Conformity assessment -- General requirements for proficiency testing*

12. APLAC MR001: Procedures for Establishing and Maintaining the APLAC Mutual Recognition Arrangements amongst Accreditation Bodies
    (see https://www.aplac.org/mr_series.html)

13. Nordic Committee on Food Analysis (NMKL) *Procedure No.8 - Measurement of Uncertainty in Quantitative Microbiological Examination of Foods* (2008)
    (see http://www.nmkl.org/index.php/en/webshop/category/prosmikro)

14. APHA: Standard Methods for the Examination of Water and Wastewater (latest edition)

15. APHA: Compendium of Methods for the Microbiological Examination of Foods (latest edition).

16. USEPA: Microbiological Methods for Monitoring the Environment

17. IANZ Technical Guide 2: Laboratory Balances Calibration Requirements (AS TG2)

18. IANZ Technical Guide 3: Working Thermometers Calibration Procedures (AS TG3)

19. IANZ Technical Guide 5: Uncertainty of Measurement, Precision and Limits of Detection in Chemistry and Microbiology Testing Laboratories (AS TG5)

20. IANZ Technical Policy 1: Measurement Traceability Policy

21. IANZ Technical Policy 2: Proficiency Testing Participation Policy

Appendix 1: Key Technical Personnel

Supervisory staff in accredited laboratories must be competent and experienced in the technical areas covered by their accreditation. They must be able to oversee the operations and cope with any problems that might arise in their work or that of their colleague or subordinates. Such staff members, formally appointed by the senior management of the laboratory, are referred to as Key Technical Personnel.

The following sets out IANZ's expectations in relation to who the laboratory management should be appointing as Key Technical Persons.

(a)   Key Technical Persons would be expected to have:

   (i)   A tertiary qualification or equivalent professional recognition in the relevant discipline. Laboratories engaged in a restricted range of repetitive work may be able to appoint Key Technical Personnel with appropriate practical experience and specific training in that work but without formal qualifications

   (ii)   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

   (iii)   A thorough working knowledge of and commitment to the requirements for IANZ accreditation and MPI Specifications for Laboratories and the Consolidated List of Tests, including the quality and technical management principles embodied in ISO/IEC 17025, relevant Specific Criteria and MPI Criteria and Specifications

   (iv)   The necessary scientific expertise and experience to be aware of and understand any limitations of the test procedures and to fully understand the scientific basis of the procedures

   (v)   Sufficient experience in the accredited laboratory to address all of the above points.

(b)   Key Technical Personnel are those individuals who are given both the responsibility and authority to:

   (i)   Develop and implement new operational procedures

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

   (iii)   Identify and resolve problems

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

(c)   Key Technical Personnel would normally be those individuals who authorise the release of all test results. However, in large laboratories such authorisations 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 Key Technical Person from taking full responsibility for the validity of the work. The authority to release results should not be confused with the authority to issue formal test reports. See Section 10.

(d)   Laboratory management may choose to appoint an individual engaged by the accredited laboratory as a consultant where their Key Technical Person responsibilities relate to work done within the scope of accreditation. There is an expectation that there would 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 should be such that they can perform their role as a technical decision maker as effectively as if they were an employee.

(e)   Staff members of an accredited laboratory who are not engaged full-time could also be appointed as Key Technical Persons. However, the circumstances in which they are called upon to exercise their Key Technical Person responsibilities and their access to and knowledge of the technical operations should be such that they are able to take full responsibility for the work they authorise or oversee.

Appendix 2: Recommended Calibration Intervals

The following table sets out the normal periods between successive calibrations 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. 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 based on the factors outlined in Section 6.

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 the staff of a laboratory have performed calibrations, adequate records of these measurements must be maintained.

IANZ has produced a number of Technical Guides with further information on some calibration procedures (e.g. balances, thermometers). Contact IANZ for further details. These can also be found at www.ianz.govt.nz/publications/technicalguides.

TYPE OF EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS	PROCEDURES
Anaerobic Jars or Cabinets	*Each use	Check condition by suitable means such as an indicator, vacuum gauge, growth of known anaerobes, etc.
Automatic burettes, dispensers and pipettors	*Initial and three months	Accuracy of and repeatability at volumes in use.
Automated microbiological dispensing equipment	*Ongoing	Verify automated dispensing of diluent and enumeration of organisms against manual standard method.
Balances *(continued on next page)*	Initial calibration and three yearly recalibrations	By an accredited calibration laboratory or; *Calibration using traceable certified masses. Refer IANZ Technical Guide AS TG 2: *Laboratory Balances – Calibration Requirements.* Staff performing calibrations need to be formally trained. Annual servicing is recommended
	Accompanied by (a) *Each weighing	Zero check
	(b) *One month	One point check using a known mass close to balance capacity.

TYPE OF EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS	PROCEDURES
Balances *(continued)*	(c) *Six months	Repeatability checks at the upper and lower ends of the scale. The standard deviation of the results can be compared against the results recorded on the last external calibration certificate.
Biological Safety Cabinets	One year	By an accredited laboratory. Documented procedures need to be in place for on-going monitoring.
Centrifuges	*One year (where the operating speed is specified)	Tachometer (mechanical stroboscope or light cell type).
Comparators and Comparison Charts	Either: *Regular replacement Or: *One year	From an approved supplier (dependent on use) Comparison against a (protected) reference comparator or chart
Computerised systems	*Instruments with electronic readouts must be calibrated as a system, including the electronic readout. The period between calibrations will depend entirely upon the nature of the instrument and the use it is being put to. *Computer programmes used to manipulate data into test results must be validated against manually calculated data upon commissioning. The results of this validation must be retained on file in the same manner as a calibration record and may be used for on-going QC checks. The programmes need revalidation if the programme is reloaded, subjected to a voltage spike or if doubt of the integrity exists. In any event it is recommended that they be revalidated periodically. It is insufficient for the laboratory to assume that proprietary programmes or programmes adopted from another accredited laboratory are inherently correct. The laboratory will need to run its own commissioning validations and subsequent QC checks.	
Conductivity Meter	*Each use *Note: If a temperature compensation probe is used, it must be calibrated. See Thermometers.*	Checked using appropriate standards in each of the scale ranges of the meter in use.

TYPE OF EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS	PROCEDURES
Cryoscope	*Each use	Checked using standard salt or sucrose solutions.
Digestion Blocks *e.g. Kjeldahl*	*Two years	Temperature variation check across working spaces using thermocouple, or recovery check with a difficult to digest standard.
Dumas instrumentation *e.g. Leco (see also Note 2)*	*Each use	Calibration against a pure certified Reference material e.g. EDTA, followed by regular with-in run monitoring of calibration stability.
Filters (membrane)	Each manufacturer's batch	Manufacturer's certification of conformance to USEPA standards, and/or; *verification checks as per Reference 16.
Furnaces (for use at specified temperatures)	*On use	Monitor temperature with an appropriate sensor.
	*Six months	Accuracy check of sensor using calibrated thermocouple or melting points of known materials.
	*Two years	Temperature variation within working space (front to back) using reference Standards (e.g. calibrated thermocouple or melting points of known materials).
Hot Plates (for use at specified temperatures *e.g. butter moisture*)	*Six months	Temperature variation across the hot plate using calibrated thermometer(s).
Karl Fischer titrators	*Each use	Known weighed amount of water.
Masses (integral, stainless steel, or nickel-chrome alloys)	Initial calibration	By an accredited calibration laboratory.
	Three years (first recalibration)	By an accredited calibration laboratory.
	Five years (successive recalibrations)	By an accredited calibration laboratory.
Mixers (*e.g. insolubility index and the like*)	*One year (where operating speed is specified)	Tachometer (technical stroboscope or light type cell).

TYPE OF EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS	PROCEDURES
Milkoscans	*One week (or as specified in standard methods) *Each use	Using skim-, low fat-, medium fat- and high fat-milk samples tested by the reference method in an accredited laboratory. Bulk milk pilot sample at regular intervals throughout a run.
Near infra-red reflectance (NIR) instruments (See also Note 1 below)	*Initial *As required (seasonal recommended) *Following each calibration or recalibration *Daily	Stable and accurate calibration for each product/constituent combination against accredited reference method results. Recalibration using up-dated calibration set. Validation of calibration using independent set of reference method results. Monitoring of calibration stability against reference method results.
pH meter	*Daily or before use Note: If a temperature compensation probe is used, it must be calibrated. See Thermometers.	Calibrate using at least two appropriate standard buffers. Buffers need to be stored in appropriate containers and marked with an expiry date.
Refrigerators	*Daily	Monitor the temperature and record.
Sieves	Endecott sieves (or other approved brands) supplied with certificates do not require checks. Working sieves can be compared against reference sieves using material typical of the samples normally subjected to sieve analysis in the laboratory.	
Spectrophotometers	Six months (wavelength and absorbance accuracy)	• By an accredited calibration agency, or • *Using traceable certified filters, or • *In accordance with MSL Technical Guide 38 (http://www.measurement.govt.nz/training-and-resources/technical-guides)

TYPE OF EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS	PROCEDURES
Spectrophotometer calibration filters		
(a) Wavelength filters	Five years	By an accredited calibration laboratory
(b) Transmittance/Absorbance filters	Annually for two years, then two yearly once stability has been demonstrated.	By an accredited calibration laboratory
Sterilisers		
(a) Autoclaves	Initial **and** following repair or maintenance	Check heating profiles of typical loads with respect to chamber temperatures to determine lag times (see Appendix 5) by an accredited calibration laboratory or,
		*Using appropriately calibrated equipment following a fully documented procedure.
		Annual servicing of steam sterilisers is strongly recommended.
	*Each use	Check the time and temperature of the cycle. Discard loads should be autoclaved for at least 30 minutes at 121 °C.
(b) Hot Air Sterilising Ovens	*Each use	Check of time and temperature. At least 160°C for 2 hours.
Tachometers	Five years	By an accredited calibration laboratory.
Thermocouples		
(a) Reference	Three years or 100 hours use (whichever is sooner)	By an accredited calibration laboratory.
(b) Working	*Six months	Single point within the working range against a reference thermometer or thermocouple.

TYPE OF EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS	PROCEDURES
Thermometers (Liquid in glass) (a) Reference	One year, then; Three years, then; Every five years thereafter *Six months	By an accredited calibration laboratory, followed by an ice point check on receipt. Ice point (See IANZ AS TG 3 - Technical Guide 3: *Working Thermometers*)
(b) Working	*Initial, then; *Six months	Check against reference thermometer / thermocouple across working range or at points of use. (See IANZ AS TG 3 - Technical Guide 3: *Working Thermometers*)
Thermometers (Resistance) (a) Reference	Initial, then; One year, then; Three years, then; Every five years thereafter. *Six months	By an accredited calibration laboratory, followed by an ice point check on receipt. *Ice point. If outside five times the uncertainty of the calibration, complete recalibration is required.
(b) Working	*Initial *Six months	*Check against reference thermometer / thermocouple across working range or at points of use. (See IANZ AS TG 3 - Technical Guide 3: *Working Thermometers*) *Ice point. If outside five times the uncertainty of the calibration, complete recalibration is required.
Thermometers (Handheld non-resistance electronic) • Working *Note: Handheld non-resistance working thermometers are generally considered of insufficient quality to be used as reference thermometers*	*One year	*Check against reference thermometer / thermocouple across working range or at points of use. (See IANZ AS TG 3 - Technical Guide 3: *Working Thermometers*)

TYPE OF EQUIPMENT	MAXIMUM PERIOD BETWEEN SUCCESSIVE CALIBRATIONS	PROCEDURES
Thermostatically controlled equipment (incubators, ovens, waterbaths)	*Daily *Two years	Monitor with temperature reading device and record. Temperature variation within working space by an accredited calibration laboratory or *Using appropriately calibrated equipment following a fully documented procedure.
Timers (stopwatches, chart recorders) (a) Mechanical (b) Electronic	*Three months *One year	Comparison against radio time "pips" or similar e.g. MSL Talking Clock (0900) 45678 Comparison against radio time "pips" or similar e.g. MSL Talking Clock (0900) 45678
Volumetric glassware (volumetric flasks, pipettes, burettes, Dean and Stark traps, solubility index tubes, butyrometers, etc.)	*Initial only	Using distilled water at critical graduations.

Notes

1   Near infrared reflectance (NIR) spectroscopy

In general, the following are expected before accreditation can be considered:

(a)   Initial calibration and recalibration

A stable and accurate calibration for each product/constituent combination sought for accreditation. The calibration must be against accredited reference methods of appropriate accuracy and precision and include at least 30 samples (preferably greater than 80) covering the range of results expected. The records of this calibration set must be available along with the results of the appropriate regression analysis.

Documented procedures must contain the laboratory's policies and procedures detailing:

(i)   The minimum number of samples in a calibration set

(ii)   The required distribution of these samples across the calibration range

(iii)   Acceptance/rejection criteria on the regression statistics.

(iv)   How often the calibration set is up-dated and regression statistics repeated, along with criteria for the acceptance or rejection of the new calibration. It is recommended calibration sets are reviewed annually.

(b)   Validation of calibration sets

Each calibration or recalibration for (a) above needs validation against an independent set of samples. The validation set should be of at least 20 samples covering the calibration range and analysed by the same accredited reference methods. Records of this validation set must be available for each calibration. The

laboratory's documented policies and procedures need to detail this requirement along with acceptance/rejection criteria of the calibration set based on the results of the calibration set.

(c)   Daily monitoring

An appropriate system for the daily monitoring (including comparisons against the reference methods and instrument parameters such as F-values) needs to be documented and implemented. These procedures are expected to detail:

(i)   Maximum allowable frequency of bias adjustments

(ii)   Maximum allowable magnitude of bias adjustments

(iii)   Required actions should these limits be exceeded

(iv)   Systems for on-going monitoring of bias adjustments and calibration stability

(v)   Authorities and responsibilities of each of the above.

2   Dumas Instruments

Calibration of these instruments requires the use of a suitably pure standard compound - usually EDTA. When setting up the instrument, the following generic criteria are expected to be applied (in addition to the manufacturer's start-up procedures).

(i)   The choice of individual determinations chosen for setting the blank must be from consecutive analyses (usually five) which agree within defined repeatability limits.

(ii)   The choice of standard compound (e.g. EDTA) determinations chosen for setting the calibration factor must be from consecutive analyses (usually five) which agree within defined repeatability limits.

(iii)   Calibrations should be verified using appropriate matrix reference samples (where available).

(iv)   Standard compounds should be analysed at regular intervals throughout a run to monitor drift and always on start-up should the instrument have been sitting idle for some time.

A record of all analyses (including blanks and standard compound determinations not chosen in the instrument calibration) must be retained.

Appendix 3: Method Validation

Validation of chemical and biological 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 requirements for method validation are detailed in ISO/IEC 17025.

The diagram on the following page (Figure 1) provides a very generalised approach to method validation that IANZ adopts when assessing the in-house validation of chemical and/or biological testing methods by individual laboratories and is considered to be consistent with the "fitness for purpose" principles embodied in ISO/IEC 17025. It is not intended to be a comprehensive reference to validation 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; in other instances, some of the elements may not need to be considered - depending on the purpose to which the method is to be applied.

Microbiological Method Validation

Most well-known texts (particularly in bacteriology) offer an array of internationally recognised standard test methods which can be employed in the analyses of particular sample types and, in most cases, these will be appropriate. Laboratory staff must be aware, however, that not always will the method be appropriate for all of their sample types.

Inhibitory foodstuffs such as spices are examples of samples where the recovery of bacteria using standard test procedures may well be prevented. Other samples may contain chemical preservatives or have pH characteristics that prohibit the growth of the organisms being analysed for, especially at low dilutions.

Methods may need modification to include neutralisers or dilution techniques, etc. to remove or reduce the inhibitory influences and allow the recovery of stressed cells. Method validation procedures are, therefore, essential in these circumstances to ensure that the procedure selected for a particular analysis of a particular kind of product is appropriate.

Modified methods should be compared against the original method if the same specifications are required to be met. This is normally achieved by analysing a sample before and after spiking with a known low number of the appropriate target organism(s) and then checking recovery. Should the expected sample types be likely to contain stressed organisms, then the use of a stressed control organism in the recovery checks should be considered. The resuscitation procedures for recovering these stressed cells may also need to be considered.

For sample analysis involving membrane filtration techniques, comparative data can be obtained using most probable number (MPN) techniques. For example, APHA *Standard Methods for the Examination of Water and Wastewater* states that for new water sources, it could be expected that 80 % of the membrane filter test results would be within the 95 % confidence limits of the multiple tube test results.

Validation of test methods should be performed under the same conditions as those of a real assay by using a combination of naturally contaminated products and spiked products.

All validation data must be recorded and stored for at least as long as the method is in force and as long as necessary to ensure adequate traceability of raw data and results.

Proficiency testing or a collaborative trial can be used to check the validity of methods, but this may not always be feasible. Analysis of samples by the proposed new method and any existing methods for the same determination is also beneficial.

Method Validation or Verification Reports

This provides some basic guidance for what should be included in a validation (verification) report for a new method for which accreditation is sought (applicable to chemical and microbiological testing).

    (a)   Title e.g. study to determine method equivalence, validation of in-house method, etc.

    (b)   Author

    (c)   Date

    (d)   Summary

(e) Objectives (analyte, scope, matrices, etc.)

(f) Applicable reference methods (are these followed, or used for guidance only to establish an in-house or modified method?). Are methods internationally accepted, validated or manufacturers' instructions?

(g) Results:

    (i) Repeatability, intermediate 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) Comparison with alternative methods, proficiency testing, reference materials

    (v) Effect of method variation (robustness – 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) Uncertainty of measurement, method limits of detection (where applicable), limits of quantitation (reporting)

    (viii) Selectivity (are there interferences from other analytes?)

    (ix) Linearity (over the intended range)

(h) Discussion (analysis of results)

(i) Conclusion (was the objective achieved, include any limitations found to be necessary)

(j) References

(k) Appendices (raw data, methods 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 (AOAC, USEPA, etc.), 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.

Figure 1: General processes for method validation in chemical and biological testing
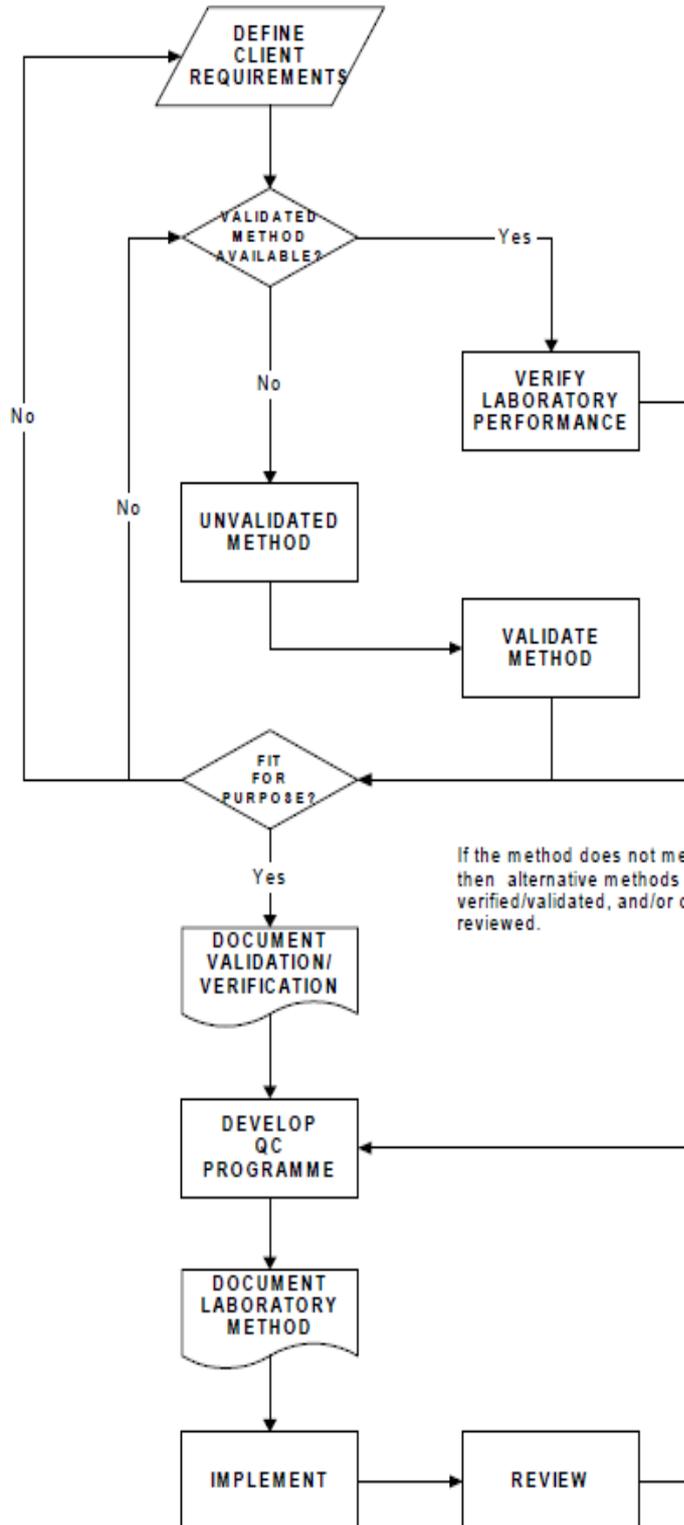
Client requirements need to be defined and should include but not be limited to:
- Why is testing being done?
- Is there a specification limit?
- What accuracy is required?
- What detection limit/precision is required?
- Turnaround time?
- Cost (including development)?

Source a validated method from:
- International standards
- National standards
- Other validated methods
  e.g. ASTM, AOAC, AOCS, APHA, etc

Verify laboratory performance through:
- proficiency testing
- reference materials
- detection limit determination
- repeatability determination
- reproducability 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
- specificity confirmation
- robustness assessment
- matrix effects/spiking
- detection limit determination
- repeatability/reproducability 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 routine quality control programme: e.g
- duplicates
- spikes
- reference materials
- proficiency testing

Following implementation a review programme should be instigated.

Appendix 4: Measurement Uncertainty

Section 9 sets out the IANZ policy for accredited RLP testing laboratories to make estimates of the uncertainty of measurements in their test results.

The following approach to estimating uncertainty of measurement is one that IANZ would suggest as being consistent with current published approaches in the international literature. It is not a mandatory specification and other approaches will be considered as equally valid provided they are sourced from published guidelines and meet the underlying principles of this process.

1. For each of the methods in the scope of accreditation providing numerical results, the laboratory should identify all components of the testing process which will contribute to the uncertainty in the final result. At this stage, it should not be necessary to quantify each component but rather just identify that it exists. Possible approaches to doing this exercise are:

   (a) By critically evaluating each step in the documented method to identify those actions/equipment etc. (i.e. components) that may affect the result.

   (b) Using the method equation and critically evaluating each variable to identify the components that will affect its value.

   The use of fish-bone diagrams and the like may be a useful tool in this regard.

2. Identify and gather or collate all available data relating to the performance of the method. The sources of such data may be external to the laboratory or data generated internally i.e.:

   (a) External data such as:

   (i) Published validation data for the standard method (which may be published in the method itself or as a separate publication) including MPN tables.

   (ii) Results from formal proficiency testing or inter-laboratory comparison programmes e.g. reproducibility (R) figures.

   (b) Internal data such as:

   (i) In-house validation studies.

   (ii) Standard reference material results.

   (iii) In-house reference material results (generally giving rise to what is known as intermediate precision).

   (iv) Precision or repeatability (r) data from duplicates.

   (v) Uncertainty of measurement values from calibration certificates.

   (vi) Variability in spike recovery data.

   It is acknowledged reference material results (both standard and/or in-house) are unlikely to be available in microbiology laboratories.

3. Conduct a gap analysis to assess which of the components identified in 1. are incorporated in the data collected in 2. Care needs to be taken in this exercise. It is important to have a clear understanding of how the data collected in 2. is generated and what it mean.

The following are a few examples which illustrate the type of issues that need to be considered:

I. Data from true duplicate sample testing will include components associated with taking the test portion from the submitted test sample (normally the taking of the test sample from the bulk is outside the control of the testing laboratory and, thus, the uncertainty component associated with sampling would not be considered) but will not normally include components of uncertainty associated with different equipment, different operators, different batches of media/reagents/standards, etc. The precision data from duplicates would in itself give an underestimation of the overall uncertainty.

II. However, and particularly in the case of microbiological testing, if as many of the testing variables (the components identified in 1. above) were to be varied in the analysis of each duplicate of each sample

III. Precision data from true duplicates gathered over a long period of time in which each of the components were varied may provide (following appropriate statistical analysis – details of which are outside the scope of this guidance) a possible estimate of uncertainty.

In microbiological testing, data from duplicate plating alone will not provide an adequate estimation of measurement uncertainty as this is generally done only on the last dilution and, thus, is only a measure of an individual's ability to repeatability plate and count. It will not include the majority of other major components of uncertainty e.g. sub-sampling, initial dilution, diluents, dilution equipment, enumeration media performance, etc.

IV. Intermediate precision from reference materials analysed repeatedly over time would include the components associated with different operators, different time, different equipment (if relevant), different media/reagents, etc. However, by their very nature, reference materials are homogenous and stable and, thus, this intermediate precision data would not include uncertainty components associated with sub-sampling analytical samples from real test samples.

In chemical testing, time issues also need to be considered – reference material data collected over weeks or months may be generated from only one batch of the analytical standard or only one batch of the stock solution. Thus, the uncertainty component associated with each of these (i.e. purity of the analytical standard, mass and volume components associated with the stock solution) would not be included.

V. Reproducibility (R) data would generally give an over-estimation of an individual laboratory's uncertainty of measurement as it includes many different operators, types of equipment, batches of media/standards and often different methods, and some of these components are not relevant to a particular laboratory's circumstance. Estimates of reproducibility are dominated by the ability of the worst performing laboratories within the data set used to calculate the reproducibility and, therefore, make no allowance for the greater ability of the better performing laboratories. It may also not reflect the actual performance of the poorly performing laboratories, and it needs to be noted that in most estimations any outliers' results for poorly performing laboratories will have been removed from the data set. It should also be noted that reproducibility could also be an under-estimate as such data is normally generated from homogenous and stable samples, which may not reflect actual practices in working laboratories.

VI. Spike recovery data needs to be carefully considered. The actual recovery itself is not a component of measurement uncertainty as it can be corrected for. However, variability in recoveries achieved is. Over time, this data will incorporate much of the measurement uncertainty components, but in chemical testing may not include those associated with analytical standards (if only one batch is used – particularly for both the recovery experiment and calibration).

In microbiological testing, spiking may also be required should the intermediate precision approach outlined in II. be considered in order to obtain statistically significant counts.

Where there are components identified in 1. which are not incorporated into the data collated in 2., these need to be independently estimated, their significance assessed and, where relevant, combined with the other uncertainty estimations.

Where these are significant, laboratories may need to review and redesign their quality control data collection programmes in order to incorporate as many of these additional components of uncertainty as possible.

Components of uncertainty which cannot be incorporated into the quality control data generated can be estimated by separate experiment, from published data, from calibration certificates, certificates of analysis or by professional judgement.

Statistical methods for the combination of components of uncertainty of measurement are outside the scope of this guidance document and readers should consult the referenced texts for further information. In microbiological testing, however, as precision data for microbiological assays are calculated from log and anti-

log transformations, the combination of this data with other uncertainty components is mathematically very complex and is usually not necessary where intermediate precision experiments have been well designed.

The examples above suggest laboratories should be able to obtain data to sufficiently cover all significant identified components of uncertainty, but these may come from different sources. It is important to ensure all major components of uncertainty are not double accounted.

Discussion

Chemical Testing

For the most part, professional judgement would suggest that the most significant contributions to measurement uncertainty in classical analytical chemistry would come from the extraction or separation of the analyte from the sample matrix. While other components should not be ignored, it is likely their contribution would be much less significant in comparison (but laboratories still need to demonstrate this). In addition, many chemical tests are empirical in nature (where the result is dependent on the method used) and, thus, if the method is followed, then method bias does not contribute to the measurement uncertainty.

The methodology suggested above for estimating measurement uncertainty will generally provide appropriate consideration of these issues and result in a reasonable estimate of the measurement uncertainty – provided the data are generated from samples of the same or similar matrix.

The model does have its limitations and, in particular, when the "extremes" of analytical chemistry are being used i.e. testing for purity of highly pure samples or testing for impurities or contaminants/residues at low levels. In these cases, components of uncertainty associated with effects, such as:

- Purity of analytical standards,
- Balance performance when weighing small amounts of analytical/reference standards, and/or
- Accuracy of volumetric glassware, etc.

(none of which would normally be considered to have a significant effect) begin to have a significant contribution. Laboratories involved in such testing need to give extra consideration to the contribution of these effects.

In chemical testing, it is ideal if the uncertainty estimation is evaluated at selected levels across the range of application of the method. However, often a test is conducted to assess compliance with a particular specification, regulatory limit or the like. In these instances, laboratories should at least estimate an uncertainty value attributable to measurement results close to the specification limit i.e. to use the specification limit as the value at which the uncertainty is estimated.

The "number of significant figures" approach and that noted in ISO/IEC 17025 should not be used as a substitute for evaluating measurement uncertainty in chemical testing.

Microbiological Testing

In the vast majority of microbiological tests, the methodology used is of an empirical nature (where the result is dependent on the method used). Therefore, if the method is followed, method bias does not contribute to the measurement uncertainty. The empirical nature of the methods arises because the measurand cannot be realised in its pure form and, thus, like traceability of measurement (see Section 6), the uncertainty associated with an actual measurement cannot also be realised. The best estimate of the uncertainty of a measured result will, therefore, come from the uncertainty associated with the performance of the method used.

The methodology suggested above for estimating measurement uncertainty will generally provide appropriate consideration of these issues and result in a reasonable estimate - provided the data is generated from samples of the same or similar matrix. Laboratories are reminded that results from plate count tests have a skewed distribution and require log transformation to approximate normal distribution statistics. Log standard deviation/confidence limits should then be calculated before anti-logging each limit independently.

In quantitative microbiological testing, it is ideal if the uncertainty estimation is evaluated at selected levels across the range of application of the method. However, often a test is conducted to assess compliance with a particular specification, regulatory limit or the like. In these instances, laboratories should at least estimate

an uncertainty value attributable to measurement results close to the specification limit i.e. to use the specification limit as the value at which the uncertainty is estimated.

Except in the case of test results obtained from MPN tables where the significant components of uncertainty are already built into the MPN tables' values, the "number of significant figures" approach and that noted in ISO/IEC 17025 should not be used as a substitute for evaluating measurement uncertainty in microbiological testing. For MPN results, IANZ will accept laboratories using the values from the 95% confidence column of the tables as a reasonable estimate of uncertainty of these results, provided laboratory estimates of precision (i.e. duplicate assays) fall within these values.

Appendix 5: Autoclaves

The basic requirement for sterilisation in an autoclave is that the contents whether liquid or solid, be exposed to saturated steam at the required temperature and for the predetermined length of time. Pressure serves as the mechanism for attaining steam temperatures above 100℃ but plays no part itself in the sterilisation process.

Sterilisation failure can occur, for example, where steam-air mixtures are present (i.e. steam saturation is not achieved). If air is not completely removed from the sterilising chamber or its contents, the residual air will contribute to the pressure indicated on the gauge but the temperature will be lower than that expected at the pressure shown.

Therefore, pressure measurements alone cannot guarantee that the appropriate temperature has been attained through the sterilisation cycle.

Measurement of temperature is essential for each autoclave cycle to ensure that the unit has been correctly vented. Therefore, autoclaves need to incorporate a temperature recording device.

This device may be a fixed or flexible probe and may be sited either in the chamber or the drain.

Temperature controllers, temperature recording charts and thermocouples need to be calibrated initially and every six months using a reference thermometer or thermocouple which, in turn, has been calibrated by an accredited calibration laboratory. Such secondary temperature calibration can be performed by the laboratory itself or by an agency accredited to perform such calibrations.

Chart recorded times and timers also need checking for accuracy. Many media contain ingredients or carbohydrates that are adversely affected by exposure to heat over time.

Pressure gauges need not be traceably calibrated but ideally should read true with respect to the required pressure at the nominated calibration temperature. Temperature calibration results will reveal deficiencies in pressure gauge readings.

Biological and chemical indicators can be used to monitor the sterilisation process but they cannot give the same level of assurance as above and, therefore, cannot alone be relied upon.

Maximum temperature registering thermometers are also designed to be indicators of temperatures achieved but not, however, of the temperature profile for any particular sterilisation cycle. Laboratories are strongly discouraged from relying on these thermometers as they cannot be calibrated under conditions of use, so there is no assurance of the accuracy of the temperature indicated. In addition, they can be easily broken causing contamination of the autoclave with mercury, with subsequent health dangers.

Domestic pressure cookers fitted with only a pressure gauge are not regarded as being suitable for sterilisation of media or decontamination of wastes because of the difficulty in adjusting and maintaining the sterilisation temperature.

Validations

Validation of autoclaves enables laboratories to demonstrate acceptable and consistent temperature of sterilisation. Heating profiles of typical loads need to be studied in relation to chamber temperatures. Placement of a thermocouple at the centre of loads and inside large volumes of liquid allows time lags to be determined when monitored with respect to the chamber temperature. Instructions for the operation of the autoclave under various load conditions can then be compiled.

The main thrust of the need to validate autoclaves is to ensure that microbiological media are not being "over-cooked" in the autoclaves. In particular, that temperatures do not exceed 121℃ and that media are not exposed to a high temperature for too long a time. Sufficient heat is needed to kill all spores whilst protecting the media from excessive heat input, thereby "over-cooking".

Please note that IANZ-accredited Medical Testing Laboratories have less stringent requirements as they are concerned with killing microbes rather than over sterilizing media.

Putting the specific requirements of the British Standard (BS2646-1:1993) aside for the moment, the following is essentially the validation data that are required.

(a) Empty Cycles

A temperature profile should be conducted on an empty chamber and not during a routine sterilisation run. This is to check that 121℃ is not exceeded and that the temperature is uniform throughout the load space. The latter may not be met if not all air is expelled and replaced with saturated steam. While useful, this exercise is not as important as the following.

(b) Media Cycles

The laboratory needs to determine what its common or standard load compositions are i.e. liquid diluents in tubes/bottles, broths, agars, equipment, etc. or a combination of any of the above. Temperature profiles **for each load type** need to be conducted to determine the temperature profile **within the media container** relative to the profile within the chamber (or, more particularly, at the temperature monitoring probe in the chamber/drain. See point (d) below).

As a rule of thumb, mixed volume loads should be avoided as it is impractical to properly control their heating cycle in a consistent manner.

The most important information gained from this data is:

(i) Heat-up times for the actual media. As a rule of thumb, these should not exceed 30 minutes to reach 121℃. Obviously, 500 mL bottles of agar will take a lot longer than 9 mL diluent tubes for example.

(ii) The lag time between the chamber reaching 121 °C and the media reaching 121℃. Again, this would be expected to be longer for, say, 500 mL agar than for 9 mL diluents.

This lag time may be added onto the sterilisation time to ensure that the media is at say 121℃ for 15 minutes.

However, it is acknowledged that laboratories may choose not to add this on if they have data to demonstrate media sterility is not a problem and to prevent the risk of "over-cooking".

Once the data from (a) and (b) are obtained, a decision needs to be made on any action to be taken, if necessary i.e. reduce load sizes or alter load compositions to ensure heat-up times and lag times are kept to a minimum.

Where significant heat-up time differences within loads of different bottle sizes are found, laboratories would be expected to adjust load contents to include only bottles with comparable times e.g. if 500 mL bottles of agar are mixed with 9 mL diluent tubes; if you then time the load for 500 mL bottles, the tubes may be heated for too long.

It is considered appropriate that load validations are conducted on the actual typical loads used by the laboratory rather than any arbitrary loading specified in the British Standard. This more realistically reflects what the autoclave is being used for. Nevertheless, if an autoclave complies in all respects to the specific requirements of the British Standard this would be accepted.

Where autoclaves are fitted with mobile "wander" probes which can be inserted into a particular bottle of media to monitor temperature of a typical load (rather than the chamber or drain temperature), then "lag times" has a different meaning altogether i.e. it would be the difference in time between the slowest and fastest bottle to reach 121℃. Validation processes need to demonstrate that this is not excessive and define where in the load this bottle should be.

(c) Destruction (or Kill) Cycles

Again, validations need to be done to establish temperature profiles within autoclave bags, pipette canisters and the like. The emphasis is not so much on "over-cooking" but rather ensuring that sterilisation temperatures are being reached for the appropriate time, e.g. 121℃ for 30 minutes.

Any lag times between the contents and the chamber are expected to be added on to the cycle. Thus, for example, if a load of autoclave bags containing petri dishes for destruction takes an extra 25 minutes to come up to 121℃ relative to the chamber, then 25 minutes is added to the cycle. For the plates to be at 121℃ for 30 minutes the chamber needs to be at 121℃ for 55 minutes and the probe in the chamber needs to demonstrate this.

Temperature Monitoring

Once the cycle parameters for each load type are established, the laboratory needs to demonstrate these are maintained each time a load is put through. This necessitates a monitoring probe within the chamber requiring calibration at 121℃. A recording device should preferably be attached.

Appendix 6: Control of Reference Organisms

Cultures of micro-organisms with defined characteristics are required for the significant majority of microbiological assays conducted by IANZ-accredited RLP testing laboratories e.g. reference or control organisms are used in a wide range of count and detection methods; test organisms are needed for micro-bioassays; and organisms with known properties are used in proficiency testing. In order to enhance the traceability requirements in microbiological determinations (Section 6) and to obtain valid results, these organisms need to be of high quality. A well maintained culture collection is an essential element of good laboratory practice.

Source of Reference Organisms

Authenticated organisms are normally obtainable in New Zealand from The New Zealand Reference Culture Collection (ESR, Kenepuru Science Centre) in a freeze-dried form with instructions for reconstitution.

Verification of Reference Organisms

Reference organisms need to be verified for their purity and identity on receipt. The level of verification of identity should be based around "fitness-for purpose" principles and the capability of the individual laboratory i.e. does the organism display the typical characteristics expected in its usual everyday use in the particular laboratory? Gram stain and biochemical reactions should also be used where the laboratory has the capability to conduct such checks.

Maintenance Guidelines

Micro-organisms have an inherent tendency to mutate in laboratory culture. It is essential, then, that laboratories use procedures to maintain their cultures in a viable and genetically stable state. Various methods have been established to preserve cultures so that minimum genetic drift occurs.

Microbiological laboratories routinely require easy access to actively growing cultures. They are required on a day to day basis for quality control, comparative testing, inoculum for bioassays and for various other reasons.
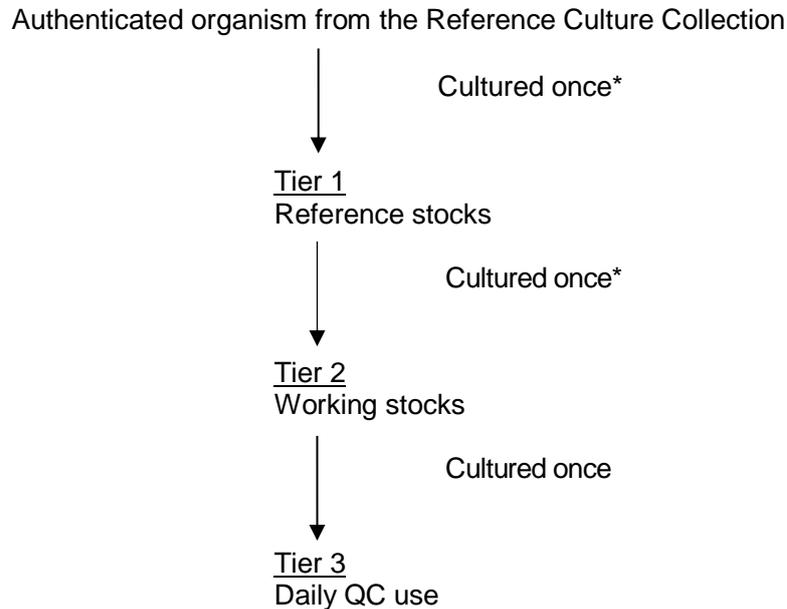
A wide variety of techniques have been used for the preservation of micro-organisms. The objective of preservation methods is to maintain the viability and genetic stability of the culture by reducing the organism's metabolic rate, thereby extending the period between sub-cultures. Most preservation methods achieve a reduction in metabolic rate by withholding nutrients, water and oxygen, by reducing the storage temperature or by a combination of these.

There is no universal method of preservation that is successful for all micro-organisms. Taxonomic groups of micro-organisms respond differently to different preservation methods. The preservation methods used reflect the different biological properties of the various groups of micro-organisms such as the bacteria, viruses, fungi, yeasts, algae and protozoa. In general, the most successful methods in terms of longevity and genetic stability employ freezing or desiccation. Where a laboratory has the facilities, cryogenic or lyophilisation procedures can be utilised.

Various microbiological method texts provide recommendations for the maintenance of a reference culture collection. The following guidelines are not intended to supersede these but to provide guidance to laboratories on the general principles involved. They are generally applicable to most organisms in common use, but there are exceptions e.g. Clostridia, which are required to be maintained by alternative processes.

Reference organisms from a recognised culture collection are used to provide reference stocks (Tier 1). Tier 2 is obtained by sub-culturing from Tier 1, and Tier 3 is obtained by sub-culturing from Tier 2. At no time should Tier 2 or Tier 3 be used to re-establish Tier 1 (see diagram below).

The underlying principle is that at no time should any culture used in the laboratory be more than three sub-cultures from the reference organism sourced from a recognised culture collection.

Authenticated organism from the Reference Culture Collection

Cultured once*

Tier 1
Reference stocks

Cultured once*

Tier 2
Working stocks

Cultured once

Tier 3
Daily QC use

Purity checks and biochemical tests as appropriate

In the majority of laboratories, one or other of the following two techniques is used:

Freezing on Beads

There are a number of preservation methods which employ the drying of organisms from the liquid state on inert substrates such as sterile soil, gelatin discs, porcelain beads, silica gel or paper discs. These methods are suitable for short to medium term preservation at -18 °C to -70℃ for periods not exceeding two or five years respectively, with good genetic stability.

The procedure essentially consists of taking a pure culture from solid media and inoculating into a suitably prepared vial containing an appropriate broth medium and unglazed porcelain beads. After agitating the beads in the broth, all excess fluid is removed from the vial with a fine tip Pasteur pipette. The vial is stored at -18℃ to -70℃. With reference to the above diagram, the frozen beads are essentially acting as Tier 1. Recovery is effected by removing a single bead aseptically from the vial and inoculating it directly onto solid media or into broth i.e. from Tier 1 directly to Tier 3. The remaining beads are available for later use.

Laboratories may choose to insert a second Tier of refrigerated storage (see below), using the beads for Tier 1 maintenance only.

Refrigerated Storage

The reconstituted authenticated organism is maintained at 4℃ on an appropriate medium and at three - six monthly intervals is used to prepare a second tier of organisms which, in turn, is used at one - two weekly intervals to prepare a third tier of ″working' organisms for day to day quality control use. All organisms are stored at 4℃. Tier 1 is replaced at one – two yearly intervals.

Generally, selective media containing carbohydrates, etc. should not be used in the maintenance of control organisms.

Storage of reference organisms must be appropriately segregated from test samples.

General

The laboratory's documented procedures need to include a section on reference organisms which must include:

(i)   Details of the organisms held in the laboratory, their source and identification, and the purposes for which they are used.

(ii)   Procedures for the verification of identity and purity of each organism.

(iii)   Details on the maintenance programme used for each organism and records maintained.

Laboratories are expected to maintain records of all their reference culture maintenance activities, including certificates from the reference culture collection, verification records and sub-culturing records for all tiers including any purity/verification checks.

Appendix 7: Media, Standards and Reagent Quality Control

1   Standards and Reagent Quality Control

Details of the preparation of all types of standard and/or reagent consumables must be recorded e.g. in a logbook, and must include results of standardisation, verification, etc. together with the date of preparation and the identity of the person who prepared them. Each container of prepared standard and/or reagent solution must be labelled as appropriate, with the date of preparation, the factor or concentration, the name or initials of the person who prepared the solution and an expiry date or be traceable to readily available preparation records containing this information. Each batch of commercially prepared consumables must be verified before use and records must be kept of these checks e.g. pH buffers, standardised solutions, biochemical test kits, rapid test kits, etc.

2   Purchasing and Preparing Microbiological Media

A media quality control programme needs to cover all media whether it be in-house prepared from basic ingredients, in-house prepared from commercially available dehydrated products, or purchased pre-prepared media.

2.1   Media Prepared In-house (generally from dehydrated stocks)

2.1.1   Purchasing

Laboratories must purchase media, which has the formulation specified by the test method. Details of these specifications, the supplier(s), expected appearance, expected pH, and methods of preparation need to be documented in the laboratory's manuals.

Records documenting batch number, date received, date opened, and results of visual inspection need to be kept for both dehydrated media and raw materials (as appropriate). The date received and the date opened may also be written on the containers. The date approved for use can be added when evaluation of performance has been completed.

When purchasing, the manufacturers" recommended shelf-life (expiry dates) as well as storage conditions required for individual items need to be considered. Annual turnover of stock is advisable and ordering of appropriate sized containers may assist overall product preservation.

2.1.2   Storage (dehydrated)

It is important that culture media in dehydrated form are prevented from taking up additional moisture from their environment during storage. The higher the moisture content the greater the possibility of degradation of the various constituents of the medium.

Dehydrated media needs to be stored in a cool, dark, minimal humidity environment e.g. not near autoclaves. Prolonged opening of a container is best avoided and careful replacement of the closure will ensure maximum possible life. Dehydrated media that are caked or cracked or show colour change should not be used.

Given the right conditions, most dehydrated media will remain in good condition for several years. However, a few products that contain ingredients of high sensitivity are less stable, especially if the moisture level is allowed to rise. Dehydrated media are generally labelled with expiry dates and should not be kept or used beyond these dates.

2.1.3   Supplements and additives

Supplements and additives (where used) need to be stored appropriately, e.g. under refrigeration where this is required. Light sensitive chemicals need to be stored in the dark.

2.1.4   Reagent water

For the preparation of media, distilled water, deionised water or water processed by reverse osmosis is generally suitable. Regular assessment of the water quality for specific chemical parameters and biological evaluation is needed and procedures are described in Appendix 8. Only water that has been tested and found

to be free from bactericidal or inhibitory compounds is to be used for preparation of culture media, reagents and diluents.

2.1.5 Glassware

Glassware washing procedures need to ensure there are no toxic residues left from detergents, disinfectants, reagents etc. Recommendations for the evaluation for inhibitory residues are also given in Appendix 8.

2.1.6 Preparation

Records must be kept of all aspects of each batch of medium prepared. A batch sheet needs to include the following information:

(a) Date
(b) Medium name, manufacturer's batch number, quantity used and volume prepared
(c) Laboratory batch number
(d) Operator's signature
(e) Sterilisation time and temperature, and any control results
(f) Post-sterilisation pH. Laboratories should also check and record the pre-sterilisation pH along with any pH adjustments made to ensure the post-sterilisation pH conforms to specifications
(g) General comments (appearance, sterility, volume, etc.).

These batch sheets could also contain the quality performance test results using reference organisms, where these checks are conducted by the laboratory prior to releasing the media for use.

When pouring plates, the correct temperature needs to be employed since an incorrect agar temperature will result in alterations to the final water content of the medium through excessive evaporation and media shrinkage. For pour plate methodologies, excessive temperatures will also result in thermal shock to the sample under test.

Where additives or supplements are required to be added after sterilisation, these need to be added at the correct media temperature to avoid any degradation of the additive.

Where a medium is prepared from basic ingredients, the batch number of each ingredient should be noted, so that when a new batch of any ingredient is used, the new complete medium can be evaluated for this difference.

2.1.7 Sterilisation

Records must be kept of all sterilisation loads. Required times and temperature of sterilisation will depend on the volumes of media dispensed, the types of media, and the performance of the autoclave being used (see Appendix 6). Appropriate chemical or biological indicators can be used to monitor autoclaving efficiency in addition to (but not as a substitute for) temperature monitoring.

2.1.8 Volumes

When the volumes of the prepared media are critical, e.g. diluents, checks of volume after sterilisation need to be made and recorded.

Generally, the accepted limits are within ± 2% of the target volume.

2.1.9 Appearance

Any pertinent comments relating to the appearance of the media during preparation should be recorded.

2.1.10 Labelling

All prepared media needs to be labelled with the date of preparation, date of expiry and the media code. This provides traceability to the preparation records.

2.1.11 Storage

Many test methodologies specify the acceptable lifetime of prepared media, and laboratories will be required to adhere to these expiry periods. In the absence of these, prepared media shelf life guidelines are detailed

below, with a note that these are guidelines only as specific media may have a much shorter shelf life. The formulation and packaging of the media however, will decide the media's basic susceptibility to deterioration during storage. The presence of an antibiotic of only moderate stability will severely limit the useful life of media. The preservation of an agar media in a Petri dish will drastically shorten the potential storage period compared with the same media stored in an effectively sealed glass bottle.

The optimum storage temperature for the majority of prepared media is about 4°C. The useful life of media will shorten as the storage temperature rises above the optimum.

Most liquid media will keep for several months at 4°C, but some have a tendency to form deposits, especially those made up at double strength. Media containing dye may fade, especially if exposed to light.

Solid media will keep for several months if stored in an airtight container. Agar gel is normally very stable, but in media where the pH is low (below 5.0), softening of the gel may take place during sterilisation, subsequent storage, or re-melting.

Storage of agar plates presents two main problems - contamination and dehydration. The length of time that plates can be kept before use will depend on the ability to avoid contamination and minimise loss of moisture. Moisture loss may be minimised by wrapping plates in plastic bags during storage at 4°C. It is important that plates of culture media not be exposed to sunlight as this may affect the performance due to the formation of peroxides.

Recommended Holding Times for Prepared Media
(Reference 16)

Medium	Holding Time
Agar or broth in loose-cap tubes at 4°C	1 week
Agar or broth in tightly closed screw-cap tubes at 4°C	3 months
Poured agar plates with loose-fitting covers in sealed plastic bags at 4°C	2 weeks

Laboratory validated expiry dates may be appropriate if the validation has been performed in accordance with recognised published methodology, however, the expiry dates stated in reference methods will always take precedence.

2.2 Pre-prepared Purchased Media

Many laboratories now choose to purchase their microbiological media in a ready-to-use form from media suppliers. Laboratories will still be required to demonstrate that the requirements outlined in 2.1 above are being met. In particular, laboratories which purchase pre-prepared media will need to implement the following:

2.2.1 Purchasing

Laboratories must purchase media which has the formulation specified by the test method. Details of these specifications, the supplier(s), expected appearance, and expected pH need to be documented in the laboratory's manuals.

A record or log of each batch of pre-prepared media receipted into the laboratory needs to be maintained, detailing:

(a) Media type and amount
(b) Manufacturer's batch number (of the prepared batch)
(c) Date received
(d) Condition/appearance on receipt (such as packaging integrity, labelling, medium appearance, contamination, leakage, etc.)
(e) Manufacture date (see below under Storage and Expiry Dates)
(f) The laboratories own expiry date (based on the manufacture date)
(g) Availability of performance evaluation certificates (see 3.2 below)
(h) An acceptance/rejection decision from an authorised laboratory staff member.

2.2.2 Storage and Expiry Dates

As discussed above, many test methodologies specify the acceptable lifetimes of a prepared media and laboratories will be required to adhere to these expiry periods. Often pre-prepared media suppliers allocate expiry dates to the batches of media supplied. Where these differ from particular method specifications, the method requirements take precedence. Any specified expiry periods apply from the date of manufacture and laboratories need to ensure this information is provided from the supplier (see 2.2.1 Purchasing above). Laboratories then allocate their own expiry date (from the date of manufacture) in accordance with their own test specification.

Many test method specifications place reasonably restrictive expiry periods on certain media, so laboratories should detail manufacturing date requirements in their purchasing specification to ensure adequate time is allowed for transportation and use before the expiry date.

Where there is no specified expiry period, laboratories should adopt the time and temperature requirements recommended in the table above.

Laboratories could opt to use the expiry dates assigned by the media manufacturer where the media manufacturer's testing laboratory is accredited for shelf life testing, and this must be able to be appropriately demonstrated from the laboratory's scope of accredited testing.

3 Evaluation of Media Performance

The ability of media to support the growth of the target organism or to selectively isolate the target organism in the presence of other fauna in an appropriate manner is one of the key method assumptions made in the validation of a microbiological method. In terms of result traceability and contribution to the measurement uncertainty, it is critical that media performance are tightly controlled and monitored.

To ascertain what media validation is required the laboratory should look first to their predominant reference methodology i.e. ISO, FDA, or MIMM etc. Where these are not clear in their requirements, the laboratory should use the guidelines below.

3.1 Media Prepared In-house

Where a medium is prepared from basic ingredients, the batch number of each ingredient should be noted, so that whenever a new batch of any ingredient is used, the completed medium can be evaluated for this difference.

Each batch of dehydrated media purchased needs to be evaluated prior to use. It is usual that each batch of media prepared (from the dehydrated batch) is checked for sterility by incubating a "blank", and checked using a positive control organism (as a method control) each time the test is performed. The use of a negative control organism as well is recommended and in many cases, it is a requirement of the reference method.

Prior to this routine use of dehydrated media, laboratories generally need to evaluate the performance of the manufacturer's batch of the dehydrated media as related to the use of media i.e. if used selectively and not for enumeration then qualitative evaluation may be all that is needed. The table below provides guidance if the requirements are not already stated in the reference methodology.

Recommended Validation Guidelines for Media Evaluation

Media Type: Media Use:	Selective Media	Non–selective Media
Enumeration and/or Enrichment	Quantitative evaluation with positive control organisms	Quantitative evaluation with positive control organisms
Non-enumerative e.g. confirmation, presence / absence	Qualitative evaluation with positive and negative control organisms	Qualitative evaluation with positive control organisms

Laboratories should establish whether the control organisms used for media evaluation need to be actively growing cultures or in a stationary phase and ensure this is included in the media evaluation procedures. The requirements may be dependent on the media being evaluated.

3.1.1 Qualitative Evaluation

For all media, the laboratory should check in a qualitative manner the ability of the media to support the growth of the target organism(s) in a typical manner, using a reference culture of the target organism(s) i.e. the positive media control. If quantitative evaluation has been carried out, this may already have been covered.

For non-enumerative media (selective), the laboratory should check the ability of the media to inhibit the growth of typical non-target organism(s) using suitable reference organism(s) i.e. the media negative control(s).

The dilution of the target organism should be such that 25-250 CFU/plate is achieved and for the non-target organism such that 250-2500 CFU/plate is achieved. The target organisms need to grow in the presence of many more non-target organisms, hence the ten-fold difference.

Laboratories need to ensure that plating / streaking techniques allow for isolation of individual colonies. This is important to allow for the above checks to assess the suitability of the growth, colony morphology, biochemical reactions, etc. under the defined incubation time and temperature conditions in which the media are to be used.

3.1.2 Quantitative Evaluation

For media used for enumerative and/or enrichment purposes, the laboratory needs to evaluate in a quantitative manner the ability of the batch of media to support, recover, or promote the growth of the target organism(s).

The following procedures are recommended for the assessment of different media types:

(a)   Evaluation of Broths

To evaluate a broth's ability to support the growth of low numbers of the appropriate organisms, 1 ml of a suspension known to contain a count of 10-20 cfu/ml of the relevant positive reference culture is added to at least 10 tubes of the broth. Incubation is according to normal requirements.

The demonstration of growth in at least 90 % of the broth tubes confirms the acceptability of the batch. Counts (by inoculation of 1 ml on an appropriate non-selective agar) at each dilution should be determined and recorded to confirm the target inoculum is correct.

(b)   Evaluation of Solid Media

Either:

(i)   Comparison of selective media (used for enumeration) against non-selective media.

Suspensions of the relevant positive reference organism are prepared and successive dilutions performed until a dilution with an appropriate low number of organisms is obtained i.e.

- Where the selective medium to be evaluated is normally used as a pour plate, 1 ml of a culture suspension of approximately 100 organisms/ml is prepared which is inoculated into the pour plate. At the same time, pour plates of a non-selective agar are inoculated. At least five sets of plates for each medium are prepared.

- Where a medium to be evaluated is normally used as a streak or spread plate, 0.1 ml of a culture suspension of approximately 1000 organisms/ml is spread on the agar surface of the plate. At the same time, plates of a non-selective agar are inoculated. At least five sets of plates for each medium are prepared.

In both instances, both sets of plates are incubated in accordance with the requirements of the selective medium. Counts at all dilutions tested should be recorded.

As most selective media will not demonstrate 100% recovery when compared with the above non-selective media, acceptable minimum recovery limits need to be established. Laboratories need to establish acceptable recoveries based on the data obtained.

And/or:

    (ii)   Comparison of a new batch of media against an approved batch of the same media.

Suspensions of the relevant positive reference organism are prepared and inoculated (as above) into both the new batch of media to be evaluated and a batch of the same media previously found to exhibit acceptable performance.

After normal incubation, the two batches of media are compared for bacterial colony size and appearance. If colonies on the new batch of media appear atypical or smaller than the colonies on the acceptable batch of media, inhibition is occurring. The colonies on each set of plates are counted. Counts at all dilutions tested should be recorded.

Colony counts on the new batch of medium should not be less than ~90% of the counts obtained on the approved batch of medium to be acceptable.

Where this methodology is used, laboratories should calculate the cumulative recovery ratio over successive batches so that any downward drift in media performance can be monitored.

And/or:

    (iii)   Comparison of a new batch of media against an approved batch of media during product testing.

The use of pure cultures may not be satisfactory to test a medium for suitability. For example, variations in the concentration of a selective ingredient might be detected only by comparing recoveries in genuine samples.

At least 5 separate product samples need to be tested in duplicate using both the new batch of media and the approved batch of media.

After incubation in accordance with normal procedures, the five sets of plates for each media batch are counted and the bacterial population per g or ml for each sample is calculated and compared. As the counts may vary markedly between samples, the results should be log transformed and the five sets of duplicate results compared. The recovery of the batch under evaluation should not be less than ~90% of the recovery of the reference batch.

If the results using the new lot of media are significantly greater than those of the accepted batch of media, the new batch is more stimulatory.

If the results are significantly less, the new lot of medium is more inhibitory.

Bacterial colony size and appearance differences between the two batches of media also need to be considered.

(c)   Evaluation of Diluents

When the volumes are critical, check of volumes after sterilisation need to be made and recorded. Diluents also need to be checked for inhibitory effects. This should be carried out in accordance with recognised methods.

3.2   Pre-Prepared Purchased Media

As with media prepared in-house, laboratories need to ensure the pre-prepared media they purchase are also subject to the evaluation requirements detailed in 3.1 above, namely:

    (a)   Selective media undergo a qualitative evaluation, and/or

    (b)   Media used for enumerative and/or enrichment purposes undergo quantitative evaluation.

An important distinction with pre-prepared media is that the required evaluation will normally be on each manufacturer's batch of the prepared media, rather than the batch of dehydrated media from which it is prepared. This is because the manufacturer's preparation processes are not generally subject to the level of control and assessment as those in an accredited laboratory that makes its own media i.e. the requirements detailed Section 2.1 above and in Appendices 6 and 9 for example.

The majority of prepared media suppliers will provide test certificates with the results of these evaluations for each batch supplied. This is accepted with the following comments:

(a) The test certificate must be from a laboratory accredited to perform media evaluation i.e. an IANZ-endorsed test certificate

(b) In their purchasing specification, laboratories should specify what level of evaluation they require of the media being purchased e.g. qualitative evaluation, quantitative evaluation, or both; and ensure an appropriate certificate is provided for each batch (see Purchasing under 2.2.1 above)

(c) A laboratory accredited for the evaluation of media is accredited only for the conduct and reporting of the evaluation testing, and not for making judgements on the quality of the media. The purchasing laboratories need to evaluate the results on the test certificate for themselves and decide whether the particular batch meets or otherwise their own internal specifications (see Purchasing under 2.2.1 above). This includes not only any evaluation results but also other parameters that may be reported such as pH, volumes, and the like.

Appendix 8: Glassware and Reagent Grade Water Evaluation

1   Detergent Residues

Modern detergents are very effective for cleaning laboratory glassware. Some, however, are highly bactericidal and care needs to be taken during rinsing procedures to ensure that all traces of the detergents are removed.

Testing for detergent residues on glassware needs to be performed at least annually or when there is a change in washing procedures or a change in detergent. The appropriate reference test should be followed e.g. References 14, 15.

A possible alternative is as follows:

(a)   Wash and rinse six glass petri dishes (or similar) according to usual laboratory practices and call these Group A.

(b)   Wash six more glass petri dishes as in (a) above but rinse with 12 successive portions of distilled or deionsed water and call these Group B.

(c)   Rinse six further glass petri dishes with detergent wash water (in use concentration), dry without further rinsing and call these Group C.

(d)   Sterilise the items comprising Groups A, B and C by usual procedures.

(e)   Add not more than 1 mL of suspension of *E. coli* or *Enterobacter aerogenes* known to contain 50-150 organisms per mL to each of the dishes comprising Groups A, B and C.

(f)   Add an appropriate amount of non-selective agar to each of the dishes and incubate according to normal procedures.

(g)   Count the number of colonies in each group of dishes.

(h)   Differences in bacterial counts of less than 15% among all groups indicate the detergent has no toxic or inhibitory effect.

Differences in bacterial counts of 15% or more between Groups A and B demonstrate that inhibitory residues are left on glassware after the normal washing procedure.

Difference of less than 15% between Groups A and B and greater than 15% between Groups A and C indicate that the detergent used has inhibitory properties which are eliminated during routine washing.

2   Reagent - Grade Water Evaluation

Only water that has been treated to free it from traces of dissolved metals, bactericidal and inhibitory compounds is to be used to prepare culture media, reagents and dilution blanks. Day to day checks on the conductivity of purified reagent water are expected to be carried out, with the generally accepted limits being <2 µS/cm for microbiology laboratories (Reference 14). Checks on pH (5.5–7.5) and total aerobic plate count (<1000 cfu/mL) should also be conducted routinely.

Testing of reagent-grade water for inhibitory (or growth promoting) properties needs to be performed at least annually or when there has been a change to or maintenance of the water purification system. More frequent evaluation may also be necessary where other quality control indicators suggest changes. The appropriate reference test should be followed e.g. References 14, 15.

Alternatively, the following procedure may be used:

2.1   Preparation of dilution water for testing

Add 1.25 mL of stock phosphate buffer solution and 5 mL of stock magnesium sulphate solution to reagent water and make up to 1 litre. Dispense appropriately and autoclave in accordance with normal procedures.

(i)   Stock phosphate solution:

34g KH_2PO_4/500 ml. Adjust pH to 7.2 and make to 1 litre volume.

(ii)   Stock magnesium sulphate solution

50 g $MgSO_4.7H_2O$ in 1 litre.

2.2   Preparation of bacterial suspension

Prepare a suspension of *E. coli* or *Enterobacter aerogenes* so that cell densities of approximately 80 cells/mL are achieved when the suspension is added to the diluent prepared in (a) above. Cell densities less than 30 cells/mL can result in inconsistent ratios; while above 100 cells/mL can result in decreased sensitivity to the nutrients in the diluent.

2.3   Assessment of dilution water toxicity

1. Plate out 1 mL of the inoculated diluent immediately into a petri dish with non-selective agar; perform in quintuplicate.

2. Allow the inoculated diluent to stand at room temperature for 60 minutes and repeat the procedure detailed in (1) above.

3. Incubate the two sets of plates in accordance with normal procedures.

4. Count the colonies on the plates at each of the 0 minute and 60 minute inoculations and calculate the % change in population as follows:

$$\frac{\text{count @ 60min - count @ 0min}}{\text{count @ 0min}} \times 100\%$$

To be considered acceptable, the % change in population should not exceed 15%.

Appendix 9: Accreditation of In Process Dairy Industry Laboratories

1   Introduction

Traditionally the New Zealand dairy industry has graded its products through final product testing in accordance with relevant product specifications. The bulk of this testing has been conducted in a single laboratory located at the site of manufacture. In general, these laboratories have also undertaken some in-process control testing but results from this testing have not been used to grade the quality of the final product.

In recent times, however, this structure has changed and this change is continuing. More and more the trend is to conduct a significant proportion of the testing in in-process laboratories attached to the manufacturing unit. The organisational structure and role of these laboratories varies from company to company - they may be on the same site as the main laboratory or on a remote site; they may be staffed by laboratory personnel or production staff; or they may (as is the increasing trend) be conducting final product testing rather than process control testing only.

The following are guidelines on the approach taken by IANZ to the accreditation of these laboratories. It must be emphasised that these are guidelines only as each situation is different and the guidelines will be interpreted to suit the particular situation. Similar principles will be applied in industries other than the dairy industry as and when an analogous situation may arise.

2   MPI Animal Products (RLP) Recognition

Under the MPI Animal Products Act, in-process dairy industry laboratories are required to be accredited if they conduct either:

(i)   Food safety testing on final product

(ii)   Truth of labelling testing on final product

(iii) Testing in support of MPI official assurances

(iv)   In-process testing, the results of which are used to justify a rationalised testing programme (for the three types of testing) on final product.

Laboratory management are reminded it is their responsibility to ensure accreditation is sought for such testing.

In-process laboratories are usually part of, attached to, or supported by a 'main' laboratory and are assessed by IANZ as part of the assessment of the main laboratory and against the same criteria as applied to the main laboratory. MPI require however, for their own purposes, separate accreditations for laboratories at different sites, whether it is at a standalone laboratory or a remote in-process laboratory associated with a main laboratory at a different site. In-process laboratories on the same site as the main laboratory will usually have its scope of accreditation maintained under the main laboratory's accreditation.

(a)   Where the laboratory is staffed by the main laboratory personnel and operates under the same quality management system, the in-process laboratory is essentially being treated as another section of the main laboratory.

If on the same site as the main laboratory, it will be included in the same scope of accreditation/Recognition. Key Technical Personnel would normally come from either the main laboratory or the in-process laboratory. In the former situation, the nominated person should be able to demonstrate a day-to-day familiarity and supervision of the in-process laboratory.

If the laboratory is staffed by the main laboratory personnel and operates under the same quality management system but is on another site, then it will have a separate accreditation but will still be assessed as part of the main laboratory A remote site laboratory will, in general, be expected to have its own Key Technical Personnel for the scope of testing. There may be some circumstances where the Key Technical Personnel may come from the main laboratory, but it is expected these individuals will have more difficulty in demonstrating a day-to-day knowledge of the systems in operation in the remote laboratory.

(b)   Where the in-process laboratory is staffed by other than the main laboratory personnel, the situation is not so straight forward. While these staff may report on most matters to their supervisor within the production team, it is mandatory for accreditation/Recognition purposes that the main laboratory has responsibility for, and authority over, the technical management of the in-process laboratory irrespective or where it is located.

This authority and responsibility must be clearly defined in the management system documentation and agreed to by the Production Management (preferably in writing). In essence, the main laboratory must have the authority on the acceptance or rejection of test results over retesting of product, and over the final grading of product.

The technical management responsibilities of the main laboratory would include:

   (i)   Training (and records) of in-process laboratory staff

   (ii)   Adherence to standard methods

   (iii)   Implementation of an appropriate quality control programme, including participation in ILCP

   (iv)   Test equipment management and calibration

   (v)   Sample management

   (vi)   Test records and reporting systems.

The in-process laboratory would also be expected to implement the normal documented quality management system requirements such as internal audits, management review, a non-conformance/corrective action system and the like.

Generally, it would be expected that the Key Technical Personnel would come from the main laboratory and should be able to demonstrate supervisory/technical management of the process laboratory i.e. to effectively fulfil the responsibilities and authority of the main laboratory as discussed above. Where a Key Technical Person is not from the main laboratory personnel, it is expected they be able to:

   (i)   Fulfil all the criteria for a Key Technical Person.

   (ii)   Have a clear understanding of the authorities and responsibilities of the main laboratory, and

   (iii)   Be in a position to fulfil these i.e. to report to the Laboratory Manager or similar should the circumstances warrant it. This would be expected to be described in a job description or similar.

3   Process Control Testing Only

Where in-process laboratories conduct testing that does not require them to be recognised by the MPI, an accredited RLP laboratory may wish to seek accreditation for this testing under the IANZ Chemical Testing and/or Biological Testing Laboratory Accreditation Programme(s). This decision is likely to be driven either by the company's own policy or perhaps by customer requirements.

The accreditation criteria detailed in this document will be applied (including those for in-process laboratories above) except for the regulatory requirements in Section 4.