# Specific Criteria for Accreditation
# **Reference Material Producers**

Fourth Edition July 2020

The NZ mark of competence
Tohu Matatau Aotearoa

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# Specific Criteria for Accreditation

# Reference Material Producers

# AS RMP C1

Fourth Edition July 2020

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# Contents

# 1 Introduction

International Accreditation New Zealand's (IANZ) Specific Criteria are an elaboration of the General Criteria for Accreditation for specific fields of test and calibration, test technologies, products or materials. They address items that are essential or most important for the proper conduct of a test or calibration, or for the production of a reference material. Specific Criteria provide detail or add extra information to the generally stated requirements of the IANZ General Criteria for Accreditation, which remains the governing document. A list of all published Specific Criteria is available on the IANZ website.

This criteria document must be read in conjunction with current issues of ISO 17034: *General requirements for the competence of reference material producers,* ISO Guide 31: *Reference material – Contents of certificates and labels,* ISO Guide 35: *Reference materials – General and statistical principles for certification*, ISO/IEC 17025: *General requirements for the competence of testing and calibration laboratories*, and the IANZ publication *Procedures and Conditions for Accreditation* (AS1), the latter document describing the organisation and operation of the IANZ Laboratory Accreditation Programme.

ISO 17034 is a general document designed to apply to all types of Reference Material Producers (RMPs). ISO 17034 requires that the production, characterisation of, and assignment of property values to reference materials be undertaken by technically competent personnel in appropriate facilities. This criteria document provides information and interpretation on classes of reference materials, staff, accommodation, equipment and other aspects of good operational management practice, which are considered to be minimum standards for RMPs accredited against ISO 17034, and ISO/IEC 17025 as applicable.

# 2 Scope

This document sets out the specific requirements an RMP needs to meet in addition to the general requirements of ISO 17034. ISO 17034: *General requirements for the competence of reference material producers,* is designed to apply to all reference material production activities and therefore needs to be interpreted with respect to the type of reference material produced.

This programme covers producers of both reference materials and certified reference materials as defined in ISO Guide 30: *Terms and definitions in connection with reference materials*. As part of accreditation as a Reference Material Producer, an accreditation scope under ISO/IEC 17025 may also be appropriate for the testing being carried out in support of producing reference materials. In this case ISO/IEC 17025 would be part of the assessment criteria.

## 2.1 Definitions

**(i) Reference Material Producer**
"Body (organisation or company, public or private) that is fully responsible for project planning and management, assignment of and decision on property values and relevant uncertainties, authorisation of property values and issue of the certificate or other statements for the reference materials it produces."

**(ii) Certified Reference Material (CRM)**
"Reference material characterised by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty and a statement of metrological traceability."

See also notes in ISO 17034.

**(iii) Reference Material (RM)**
"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."

See also notes in ISO 17034.

**(iv) Homogeneity**
"The degree to which a property or constituent is uniformly distributed throughout a quantity of material and between separate units of the same material". ISO/IEC Guide 99.

**(v) Stability**
"The ability of a property value to remain unchanged, within a stated uncertainty, under given storage conditions and a specified timeframe". ISO/IEC Guide 99.

**(vi) Measurement Uncertainty**

"Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used". ISO/IEC Guide 99

In addition to this document, there are supplementary criteria documents applicable to testing laboratories which have their own unique set of criteria and may form part of the assessment depending on the extent of testing or calibration (to ISO/IEC 17025) undertaken by the producer.

AS LAB C1 *Specific Criteria for Accreditation – Biological Testing*

AS LAB C2 *Specific Criteria for Accreditation – Chemical Testing*

AS LAB C3 *Specific Criteria for Accreditation – Electrical Testing*

AS LAB C4 *Specific Criteria for Accreditation – Mechanical Testing*

AS LAB C5 *Specific Criteria for Accreditation – Metrology & Calibration*

AS LAB C6 *Specific Criteria for Accreditation – Applied Physics*

AS LAB C7 *Specific Criteria for Accreditation – Medical Testing*

AS LAB C12 *Specific Criteria for Accreditation – MPI Recognised Laboratory Programme*

# 3 Categories of Reference Materials

Accreditation by IANZ does not constitute a blanket approval of all reference material producer activities. Therefore a means of identifying those activities for which accreditation is granted is necessary. Appendix 1 provides a basic list of possible categories of reference materials which can be used to describe the scope of accreditation of an RMP. If the (C)RM does not fit into any of the main four categories, it may be listed as miscellaneous or a new category may be developed. The scope of an accredited RMP is intended to give an overview of the areas of competence of that producer, not list specific materials which are produced. The accreditation process of the individual RMP will result in an appropriate description of the RMP's scope of competence.

# 4 Environment

Accommodation requirements for an RMP can vary widely depending on the nature of the work undertaken. Irrespective of where reference materials are produced (RMP or subcontractor) and certified there must be adequate space and storage facilities for carrying out material preparation and packaging, testing, reporting etc. Different conditions will be appropriate and necessary for the production and the testing of the reference materials, and also for the different types of materials.

Factors that may need to be considered include but are not restricted to:

(a) Isolation from sources of stray electric and magnetic fields, mechanical vibration etc. (as appropriate)

(b) Adequate ventilation where fumes are created during the manufacturing or testing process

(c) Suitable equipment and areas for testing and characterisation

(d) Suitable areas for the preparation and storage of reference materials. Storage facilities must be sufficient to allow for separation of all candidate materials and reference materials (from other chemicals). Long term storage must be in suitable conditions for stability trials

(e) Monitoring of critical conditions which could affect the integrity of the final (C)RM.

# 5 Traceability of Measurement

## Certified Reference Materials

RMPs may produce either reference materials and/or certified reference materials. The requirements for certifying a reference material are considerably more rigorous than those for producing a reference material.

In particular as the definition above in 2.1 implies:

- A CRM's properties must be characterised by a metrologically valid procedure such as those in ISO Guide 35
- It must be accompanied by a certificate that provides those values; along with:
- The associated uncertainty established using ISO/IEC Guide 98-3, *Uncertainty of measurement-Part 3: Guide to the expression of uncertainty in measurement (GUM)*
- A statement of metrological traceability.

The *International Vocabulary for Metrology (VIM)* defines metrological traceability as the:

"..property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty."

The "reference" referred to can be:

- One or more International System of Units (SI) or
- A measurement procedure or
- A measurement standard (including another CRM - preferably of higher pedigree).

Where the property value of a CRM is an SI base or derived unit then the normal IANZ traceability rules apply:

Measurement traceability must be established for all critical* results of measurements, either:

(a) Directly to the New Zealand National Measurement Institute (Measurement Standards Laboratory, NZ) or another such national measurement institute (e.g. National Physical Laboratory - UK, National Measurement Institute - Australia, etc.) belonging to the CIPM mutual recognition arrangement for national metrology institutes.

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

**Critical measurements/calibrations are those that will significantly affect the accuracy or proper performance of tests, and thus the uncertainty in the assigned value of a (C)RM*.

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 measurement traceability to national standards.

It should be noted that traceability and uncertainty are closely aligned and neither has much meaning in the absence of the other. Traceability can be understood as the demonstration of quantified links and their uncertainties between the results of a measurement and the value of national or international measurement standards or reference methods.

Traceability is not an end in itself. The purpose of establishing traceability of the results of measurements is to ensure that the results can be stated with quantified uncertainties in the appropriate measurement units (often SI measurement units) so that they are in fact what they are purported to be and are accurate, are comparable with the values obtained by other measurements made by other methods in other domains, are stable in the long term, and are not subject to systematic effects or extraneous factors.

An example of a CRM would be human serum with an assigned quantity value for the concentration of cholesterol and associated measurement uncertainty stated in an accompanying certificate, which includes a statement of metrological traceability.

Note that in this case metrological traceability would most likely be through a national or international documented measurement procedure or another certified reference material or a combination of both. An uncertainty budget would need to be established using the GUM process.

## Reference Materials

While it is desirable for RMPs to assign guidance values and uncertainties to reference materials, that may not be possible. For reference materials the mandatory requirements are:

- Established homogeneity and stability as fit for purpose

- Verification that replacement batches of RMs have equivalent properties and uncertainties to those batches they replace.

# 6 Equipment Management and Calibration

Production and laboratory equipment, and its suitability, ranks on a level equal to the competence of the staff using it. An accredited RMP and associated laboratory (if applicable, or a subcontractor) will be expected to possess and maintain a documented management system compliant with ISO/IEC 17025, all equipment necessary to carry out the activities (including testing) required for the production of RMs and CRMs requested for inclusion in the scope of accreditation.

Requirements for, and guidelines on, calibration requirements and re-calibration intervals for specific items of test and calibration equipment are detailed in the IANZ Specific Criteria Schedules relevant to the type of testing and calibration carried out by the RMP and/or its sub-contractors as listed above in section 2.

If equipment being used in testing is located at a subcontractor, it is the responsibility of the RMP to ensure that the subcontractor has adequate systems in place and is meeting these requirements.

Equipment used in the production, processing, purifying, packaging and storing of the (C)RMs needs to be such that the integrity and quality of the product is not compromised.

# 7 Staff and Key Technical Personnel

An accredited RMP must have at least one staff member who is competent in the work being undertaken. Both ISO 17034 and ISO/IEC 17025 give the general requirements for staff and management.

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

The expected roles and qualifications of a Key Technical Person are given in Appendix 2.

(a) Appointment of Key Technical Personnel will be the responsibility of a designated senior staff member who is a member of the RMP's senior management team. RMPs 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 RMP 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 RMP's quality manual or as a separate document, but must be maintained up-to-date at all times. The technical scope for each individual will be described in a manner to suit the RMP's circumstance and organisational structure, but there must be at least one Key Technical Person appointed for each test/material, or group of tests / materials in the RMP'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 the Application for Accreditation or Reassessment documentation provided prior to the full reassessment. The list will also be reviewed with RMPs during their surveillance assessment

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

(e) In addition to the RMP'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 by IANZ for each appointed Key Technical Person in the Application for Accreditation/Reassessment documentation described above. This information is also be expected to be provided to IANZ when new Key Technical Personnel are appointed and notified to IANZ outside of assessments

(f) Where the RMP loses the sole Key Technical Person for all or part of their scope of accreditation, and no new appointment is made by the RMP management then the RMP's accreditation (or part thereof) will be suspended until such time as a new appointment is notified to IANZ. This would not affect existing stocks of (C)RM's that had been produced and signed for by the departed KTP

(g) 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 RMP to be assured the RMP's systems and integrity of the RMP's certificates will continue to be maintained

(h) All IANZ-endorsed certificates issued by an accredited RMP must be signed or authorised by a Key Technical Person nominated by the RMP. See Section 11.2.1.

The appointment of Key Technical Personnel effectively means the responsibility for qualification of key individuals within the RMP lies with the RMP management. IANZ Assessment Teams are not obliged to 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 RMP is continuing to maintain the requirements for accreditation, it is not the individual who is considered to have "passed" or "failed" but rather the RMP 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 Production Test/Methods

The RMP will be assessed against ISO 17034 and applicable requirements of ISO/IEC 17025 relating to testing or calibration. The RMP may choose to seek separate accreditation to ISO/IEC 17025 for its testing laboratory (chemical, biological, mechanical etc.) in which case the laboratory needs to apply for accreditation as a testing laboratory in its own right.

An RMP who is undertaking testing as part of the production process (to determine homogeneity and stability and to characterise the candidate reference material) will be assessed against the applicable requirements of ISO/IEC 17025 and ISO Guide 35.

See the applicable Specific Criteria for Accreditation, as listed in section 2, for further information on test method classifications in relevant disciplines.

No amount of testing of the final (C)RM can improve the actual homogeneity and stability of the produced material to be used as the reference material. Exhaustive testing can only provide a measure of probability of how well the final product conforms to a known specification. Therefore due consideration must be given to the production planning, production control, accommodation and environmental conditions, material handling & storage and material processing sections of 17034. The RMP will be assessed on its compliance with these sections, whether or not it actually performs them or they are subcontracted.

Where there are technical methods available for the production of items to be characterised as reference materials (e.g. ISO 6141: *Requirements for certificates for calibration gas mixtures*; ISO 6142-1: *Gas analysis – Preparation of calibration gases, gravimetric method)*, these will be used as part of the assessment process. These should be supplied to IANZ by the RMP prior to the assessment.

# 9 Subcontractors

"*Body (organisation or company, public or private) that undertakes aspects of the processing, handling, homogeneity and stability assessment, characterisation, storage or distribution of the reference material on behalf of the reference material producer."*

See also Note in ISO 17034. The RMP shall have a written agreement with its subcontractors.

Where a subcontractor undertakes any part of the process (manufacturing, characterisation, homogeneity / stability testing) for the candidate reference material, the RMP will need to ensure that they have documented evidence that the subcontractor is in compliance with all the relevant clauses of ISO 17034, ISO/IEC 17025 and ISO Guide 35 (the latter two if performing testing for characterisation or homogeneity/stability determinations).

It is the responsibility of the RMP to select the subcontractor, ensure technical competence of the subcontractor, and to be able to demonstrate this to the assessment team.

The RMP management system and organisation chart will need to clearly define the roles and relationships with subcontractors. The RMP needs to have personnel operating under its management system who have

sufficient knowledge of the subcontractor's tasks to evaluate the subcontractor's activities. Also see Appendix 3.

As part of the assessment process the assessment team will investigate all matters relating to ISO 17034 and this may also require an on-site assessment of relevant work carried out by the producer's subcontractors. Should there be any changes to arrangements between the RMP and subcontractors, IANZ will need to be informed promptly. IANZ will review the new subcontractor arrangements and determine whether accreditation requirements continue to be met or if further information is required.

Serial subcontracting (i.e. subcontracting of subcontracted work) is not permitted. All subcontractors need to be directly linked to the RMP.

# 10 Assignment of Property Values and Uncertainties

The RMP must be responsible for assigning the property values, authorisation of property values and issuing the certificate. As with project planning, these activities need to be carried out by the RMP and cannot be carried out by subcontractors.

The basis for any evaluation of measurement uncertainty in the assigned value is ISO Guide 98-3: *Guide to the Expression of Uncertainty in Measurement (GUM)* and the principles and methodologies expressed in this document need to be applied. It is mandatory for CRM's and recommended for RM's.

ISO Guide 35: *Reference Materials – General and statistical principles for certification* contains valid methods to assign values to the properties of reference materials, including the evaluation of their associated uncertainty. At some stage during the production process the RMP will need to decide, based on analytical results and experience, whether the material is suitable to be a CRM or will need to be an RM.

Where property values cannot be established that meet the criteria for certified properties but these values may be of use to the user, these values may be included on the certificate but must be clearly marked to avoid confusion with certified values. These values may be obtained during the characterisation of the reference material.

According to the complexity of the work carried out and the information supplied, it is likely to be necessary for the assessment team to include a statistician to review work carried out by the RMP.

# 11 Records and Certificates

## 11.1 Records

An adequate records system is essential. Many organisations have developed forms (pro-forma sheets) for all of their routine work. These are generally the preferred option as their use prompts the recording of all the required information, maintains consistency and increases recording efficiency.

The RMP must also hold copies of all data and records generated by any non-accredited subcontractors during the production of a (C)RM.

## 11.2 Certificates

The contents of the certificate accompanying the (C)RM must meet the requirements of ISO Guide 31 *Reference Materials – Contents of Certificates and Labels* and the certificate must be signed by a Key Technical Person.

Certificates may only be produced to accompany CRM's. Included in ISO Guide 31 are many 'should' statements related to information on certificates that are not requirements; however, these may be considered on a case-by-case basis as applicable to the (C)RM.

Information provided with Reference Materials (non CRM's) is to be in the form of a Product Information Sheet (however named) but cannot be called a Certificate. The difference between the two forms of information provided has been introduced to attempt to address confusion in the market place where RM's were accompanied by a certificate.

RMP's must retain an exact copy of all certificates / product information sheets issued and any subsequent information supplied to customers relating to the (C)RM. These copies must be retained securely and be readily available for the period specified in the organisation's documented policies.

The RMP should take care not to confuse test reports for internal purposes with the certificate of analysis issued with the Certified Reference Material. Certificates are to provide information to the user, they need to be clear and unambiguous, can be more than one page and do not need to follow the order of items listed in ISO Guide 31.

### 11.2.1 IANZ-Endorsed (C)RM Certificates

Accredited RMP's are required to include reference to their accreditation in the certificates they issue. The general rules governing the use of IANZ endorsements are detailed in Appendix 1 of the IANZ publication *Procedures and Conditions of Accreditation* (AS 1).

Where a reference material produced is not under the scope of accreditation, the certificates must not include the IANZ accreditation symbol or any reference to the RMPs accreditation. When a material has been produced that is covered under the scope of accreditation, IANZ would expect that the IANZ endorsement be used.

# 12 References


1. ISO 17034: 2016 – *General requirements for the competence of reference material producers*
2. ISO Guide 30: 2015 – *Reference materials - selected terms and definitions*
3. ISO Guide 31: 2015 – *Reference materials – Contents of certificates and labels and accompanying documentation*
4. ISO Guide 35: 2017 – *Reference materials – Guidance for characterisation and assessment of homogeneity and stability*
5. ISO/IEC 17025: 2017 – *General requirements for the competence of testing and calibration laboratories*
6. *Procedures and Conditions for Accreditation* (AS 1), IANZ
7. ISO Guide 98-3: 2008, *Uncertainty of measurement – Part 3: Guide to the Expression of Uncertainty in Measurement* (GUM:1995), ISO/BIPM/IEC/IFCC/IUPAC/IUPAP/IOML
8. ISO Guide 99: 2007 - *International Vocabulary of Metrology – Basic and general concepts and associated terms (VIM)*
9. Asia Pacific Laboratory Accreditation Co-operation (APLAC) TC008 – *Requirements and Guidance on the Accreditation of a Reference Material Producer*
10. ILAC P10 – *Policy on Traceability of Measurement Results*

# Appendix 1: Classes of Reference Materials

These principal categories are subdivided into sub-categories as indicated in the following list. It should be noted that these sub-categories are indicative only. Other sub-categories can be included as required.

## CATEGORY A: CHEMICAL COMPOSITION

### A1: METALS

#### A1.1 Ferrous

a. Steels
b. Irons
c. Gases in metals

#### A1.2 Nonferrous

a. Aluminium alloys
b. Copper base alloys
c. Lead base alloys
d. Tin base alloys
e. Brasses
f. Bearing alloys
g. Titanium base alloys
h. Zirconium base alloys
i. Gases in metals

#### A1.3 Special alloys

#### A1.4 Refractory metals and alloys

#### A1.5 Rare earth metals

#### A1.6 High purity metals

a. Solid forms
b. Spectrochemical materials
c. Spectrochemical solutions

### A2: INORGANIC REFERENCE MATERIALS

#### A2.1 Ores and minerals

#### A2.1 Cements, clays and related products

#### A2.3 Ceramics, glasses and refractory oxides

a. Carbides
b. Glasses

#### A2.4 Agricultural chemical and fertilisers

#### A2.5 Solid fuels

Coal and coke

#### A2.6 Pure Chemicals

a. Stoichoimetry standards
b. Chromatography standards
c. Pharmaceutical materials
d. Cosmetic materials

#### A2.7 Stable isotope materials

### A3: ORGANIC REFERENCE MATERIALS

#### A3.1 Pure organic compounds

a. Compounds for elemental analysis
b. Compounds for molecular weight
c. Chromatography standards
d. Illicit drugs & their metabolites
(Also see A8 forensic reference materials)
e. Illicit drugs
f. Therapeutic drugs
g. Veterinary drugs
h. Steroids
i. Pesticides, herbicides, acaricides etc
j. Metabolites of any of the above
k. Priority pollutants
l. Fine chemicals
m. Pharmaceutical materials
n. Cosmetic materials
o. Isotopically labelled compounds

#### A3.2 Agricultural materials and fertilisers

#### A3.3 Foodstuffs

a. Proximate analysis
b. Nutritional properties
c. Vitamins
d. Other food additives
e. Toxins
f. Trace elements
g. Trace organics

#### A3.4 Plastics and rubbers

a. Hardness
b. Natural rubber content
c. Identity

#### A3.5 Petroleum products

a. Fuels and lubricants
b. Transformer oils
c. Heat exchange fluids

#### A3.6 Vegetable oils and fats

a. Fatty acid profile
b. Triglyceride composition

## A4: ENVIRONMENTAL REFERENCE MATERIALS

### A4.1 Soils and sludges

a. Trace elements
b. Mineral content
c. Trace organics
d. TCLP leachate

### A4.2 Ashes

a. Fly ash from coal and coke
b. Incinerator ash

### A4.3 Waters

a. Potable water
b. Fresh water
c. Sea water
d. Industrial waste water
e. Treated sewage

### A4.4 Plant Material

a. Trace elements
b. Mineral content

### A4.5 Marine

a. Fish
b. Molluscs
c. Plankton

### A4.6 BOD reference compounds

### A4.7 Miscellaneous biological compounds

(e.g. human hair)

## A5: HEALTH & INDUSTRIAL HYGIENE

### A5.1 Clinical laboratory solutions

### A5.2 Ethanol solutions

### A5.3 Toxic substances in urine

a. Toxic metals
b. Fluoride
c. Mercury

### A5.4 Drugs of abuse in urine

### A5.5 Drugs of abuse in hair

### A5.6 Materials on filter media

### A5.7 Trace elements in blank filters

### A5.8 Lead in paint (powder & sheet form)

### A5.9 Respirable silica

## A6: ENGINE WEAR MATERIALS

### A6.1 Metallo-organic compounds

### A6.2 Wear metals in oil

## A7: ANALYSED GASES

### A7.1 Gas mixtures

### A7.2 Trace volatile organic compounds

## A8: FORENSIC REFERENCE MATERIALS

### A8.1 Ethanol reference materials

a. Ethanol
b. Ethanol, aqueous solutions containing 0.050, 0.150, 0.250, g/100mL

### A8.2 Drugs (individually named) and metabolites

In whole human blood and urine (*metabolites to include glucuronides)
See also A3.1 Pure Organic Compounds

### A8.3 Glasses

a. Bottle
b. Window
c. Automotive
d. Spectacle

### A8.4 Paints

a. Automotive
b. Architectural

### A8.5 Accelerants

Flammable liquids and residues thereof

### A8.6 Explosives and primers

### A8.7 Gunshot residues

### A8.8 Noxious substances

a. Crowd control agents

### A8.9 Document examination

## A9: ION ACTIVITY

### A9.1 pH standards

### A9.2 Ion selective calibrants

### A9.3 Conductivity standards

### A9.4 Buffer systems

## CATEGORY B: BIOLOGICAL & CLINICAL PROPERTIES

**B1: GENERAL MEDICINE**

- **B1.1 Human serum materials**
  (Powder and solution forms)

**B2: CLINICAL CHEMISTRY**

- **B2.1 Proteins**
- **B2.2 Apolipoproteins**
- **B2.3 Enzymes**
- **B2.4 Hormones**
- **B2.5 Trace elements lead and cadmium**

**B3: TISSUE PATHOLOGY**

**B4: HAEMATOLOGY AND CYTOLOGY**

- **B4.1 Blood serum**

**B5: IMMUNOHAEMATOLOGY**

**B6: IMMUNOLOGY**

**B7: PARASITOLOGY**

**B8: BACTERIOLOGY AND MYCOLOGY**

- **B8.1 Reference cultures**
- **B8.2 Antibiotics**

**B9: VIROLOGY**

**B10: OTHER BIOLOGICAL & CLINICAL REFERENCE MATERIALS**

**B11: FORENSIC REFERENCE MATERIALS**

a. Purified DNA of known and continuing genetic composition
b. Human, primate and animal blood
c. Animal hairs
d. Fibres (also see C7.1 and C7.3)

## CATEGORY C: PHYSICAL PROPERTIES

**C1: REFERENCE MATERIALS WITH OPTICAL PROPERTIES**

- **C1.1 Optical rotation**
- **C1.2 Refractive index**
- **C1.3 Spectral absorbance**

a. Visible
b. Ultraviolet
c. Infrared

- **C1.4 Specular reflectance**
- **C1.5 Colour**

a. White reference material (opal glass)
b. Ceramic tiles

**C2: REFERENCE MATERIALS WITH ELECTRICAL & MAGNETIC PROPERTIES**

- **C2.1 Dielectric strength**
- **C2.2 Resistivity**
- **C2.3 Magnetic susceptibility**

**C3: REFERENCE MATERIALS FOR FREQUENCY MEASUREMENTS**

**C4: REFERENCE MATERIALS FOR RADIOACTIVITY**

- **C4.1 Radiation dosimetry**
- **C4.2 Radiopharmaceuticals**
- **C4.3 Labelled compounds**
- **C4.4 Natural matrix materials**
- **C4.5 Carbon-14 dating**

**C5: REFERENCE MATERIALS FOR THERMODYNAMIC PROPERTIES**

- **C5.1 Calorimetry**
- **C5.2 Thermal conductivity**

a. Metals
b. Pyrex glass
c. Resin-bonded fibre board

- **C5.3 Vapour pressure**
- **C5.4 Thermal expansion**
- **C5.5 Thermal resistance**
- **C5.6 ITS-90 temperature fixed point**
- **C5.7 Curie point**
- **C5.8 Boiling point**
- **C5.9 Melting point**
- **C5.10 Thermal analysis standards**

**C6: REFERENCE MATERIALS FOR PHYSICO-CHEMICAL PROPERTIES**

- **C6.1 Density**
- **C6.2 Viscosity**
- **C6.3 Surface tension**
- **C6.4 Molecular weight**

**C7: REFERENCE MATERIALS FOR FIBRE BOARD IDENTIFICATION**

- **C7.1 Natural fibres**
  a. Animal hairs
  b. Plant fibres
- **C7.2 Synthetic fibres**
  a. Organic polymers
  b. Inorganic
- **C7.3 Asbestos fibres**
  a. Crude fibres
  b. Mounted specimens for fibre counting

**C8: REFERENCE MATERIALS FOR OTHER PROPERTIES**

- **C8.1 Shear testing of powders**
- **C8.2 Minerals for x-ray diffraction**

## CATEGORY D: ENGINEERING PROPERTIES

**D1: SURFACE FINISH**

- **D1.1 Surface roughness**
- **D1.2 Corrosion**
- **D1.3 Microhardness**
- **D1.4 Abrasive wear**
- **D1.5 Properties of films and surfaces**
  a. Nominal thickness

**D2: SIZING**

- **D2.1 Particle size**
  a. Particulate materials
  b. Latex sphere suspensions
- **D2.2 Surface area**

**D3: NON-DESTRUCTIVE TESTING**

- **D3.1 Dye penetrant test bocks**
- **D3.2 Artificial flaw for eddy current**
- **D3.3 Magnetic particle inspection**

**D4: HARDNESS**

- **D4.1 Rockwell hardness**
- **D4.2 Izod hardness**

**D5: IMPACT TOUGHNESS**

- **D5.1 Charpy V-notch test blocks**

**D6: TENSILE STRENGTH**

**D7: ELASTICITY**

**D8: CREEP**

**D9: FIRE RESEARCH**

## CATEGORY E: MISCELLANEOUS PROPERTIES

# Appendix 2: Key Technical Personnel

Supervisory staff in accredited RMP's 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 RMP, are referred to as Key Technical Personnel.

The following sets out IANZ's expectations in relation to who the RMP 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. RMPs 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 RMP operation to ensure the integrity of assigned values 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 RMP on a day to day basis

  (iii) A working knowledge of and commitment to the requirements for IANZ accreditation, including the quality and technical management principles embodied in ISO 17034 and relevant Specific Criteria

  (iv) The necessary scientific expertise and experience to be aware of and understand any limitations of the production and test procedures used to support assigned values, and to fully understand the scientific basis of the procedures

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

(b) Key Technical Personnel are those individuals who are given both the responsibility and the 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 final acceptance of assigned values and (C)RM test certificates. However in large RMPs 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 (C)RM and certificate results. The authority to release (C)RM should not be confused with the authority to issue formal certificates. See Section 11.

(d) RMP management may choose to appoint an individual engaged by the accredited RMP 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 RMP 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 RMP 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 3: Possible RMP / Subcontractor Arrangements

The RMP's management system will need to clearly define the roles and relationships with their subcontractors. It is the responsibility of the RMP to confirm the technical competency of the subcontractor for the work they undertake and records in support of this will need to be available.

RMP's also need to ensure they hold copies of all the data and records generated by their non-accredited subcontractors in the production of a reference material. Table 1 below includes possibilities for how tasks included in the production of reference materials could be allocated. This is not an exhaustive breakdown and other arrangements may be considered if appropriate.

**Tasks in bold must be performed by the RMP**.

R Tasks performed by the RMP

S Tasks performed by a subcontractor

P Tasks performed by an external party (supplier that is not a subcontractor as defined in either 17034 or ISO/IEC 17025) such as a distributor or storage services.

# If performed by subcontractors, the RMP needs to ensure technical competence.

* When these tasks are performed by a subcontractor, any conclusions reached in regard to the tasks are the responsibility of the RMP.

** Testing, calibration and measurement activities involved in reference material production and preparation need to comply with the relevant parts of ISO/IEC 17025

The following are possible modes of operation for RMP's:

(a) One single organisation produces the candidate reference material and assigns the property values based on their own organisations measurement results (Type 1 in the table below)

(b) An organisation produces the candidate reference material and assigns the property values based on the measurement results from other (subcontractor) laboratories. The certificate is issued by the producer (Type 6 in the table)

(c) An organisation produces the candidate reference material and is responsible for the homogeneity and stability studies. The property values are characterised by a National Measurement Institute (for example) or an external accredited laboratory. The producer sells the reference material (Type 8 in the table)

(d) An organisation subcontracts the production of a candidate reference material and assigns the property values based on measurement results from their own laboratories. The organisation that issues the certificate sells the reference material (Type 2 from the table)

(e) An organisation subcontracts the production of the candidate reference material and all laboratory work necessary to assign the reference material values. The certificate is issued by the RMP and the reference material is distributed by the RMP or an external party (Type 5 from the table)

Note: An RMP may operate in different modes at different times and/or for different (C)RM's. This needs to clearly defined in the RMP's management system documentation and shall be taken into account in the assessment approach that is adopted by IANZ.

## Table 1: Possible RMP / Subcontractor Arrangements

| Stages/Tasks of RM Production | Accreditation Requirements | Responsible Organisations | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| **Production planning** | ISO 17034 | **R** | **R** | **R** | **R** | **R** | **R** | **R** | **R** |
| #Material preparation** | ISO 17034 / ISO/IEC 17025 | R | S | S | S | S | R | S | R |
| #Homogeneity/stability testing | ISO 17034 / ISO/IEC 17025 | R | R | R | S* | S* | S* | S* | R |
| #Characterisation of property values | ISO 17034 / ISO/IEC 17025 | R | R | R | S* | S* | S* | R | S* |
| **Assignment of and decision on property values** | ISO 17034 / ISO/IEC 17025 | **R** | **R** | **R** | **R** | **R** | **R** | **R** | **R** |
| **Authorisation of property values and issue of certificate** | ISO 17034 / ISO Guide 31 | **R** | **R** | **R** | **R** | **R** | **R** | **R** | **R** |
| #Handling and storage (including post certification testing) | ISO 17034 / ISO/IEC 17025 | R | R | S | R | S | S | S | R |
| Distribution and post distribution service | ISO 17034 | R | R | P/R | R | P/R | R | P/R | R |