General Accreditation Criteria

Reference Material Producers

ISO 17034 Standard Application Document

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Reference Material Producers ISO 17034 Standard Application Document

This document provides interpretative criteria and recommendations for the application of ISO 17034 for Reference Material Producers (RMP) for both applicant and accredited facilities.

Applicant and accredited facilities must also comply with all relevant NATA accreditation criteria (refer to *NATA Procedures for Accreditation).*

The clause numbers in this document follow those of ISO 17034 *General requirements for the competence of reference material producers* but since not all clauses require interpretation the numbering may not be consecutive.

6 Resource requirements

6.1 Personnel

6.1.6 Personnel records should include evidence, where relevant, by professional or regulatory bodies (for example licensing and registration).

NATA will list individuals, however named (previously approved signatories), where there is a regulatory framework such as for Legal Metrology or is covered in a Deed of Agreement, Memorandum of Understanding or other binding agreement with a third party. The facility must nominate individuals who are authorised to release reference materials and NATA will formally acknowledge these individuals in the report on assessment.

6.2 Subcontracting

6.2.4 The following should be considered during review of the subcontractor:

- property value, testing or determination (homogeneity, stability, etc.) required;
- method(s) used;
- required measurement uncertainty or accuracy of the determination/testing;
- metrological traceability;
- reporting requirements;
- performance of proficiency testing activities (where suitable and applicable);

6.2.5 A competent subcontractor is for example, but not limited to, an accredited NATA facility or a facility accredited by a signatory to a Mutual Recognition Arrangement. The accreditation status of subcontractors should be regularly reviewed to ensure currency.

Where a non-accredited subcontractor is used, records of the RMP's review of the subcontractor's competence must be maintained.

7 Technical and production requirements

7.6 Measurement procedures

Facilities must ensure they comply with NATA's *Metrological Traceability* for all tests, measurements and calibrations that have a significant effect on reported values.

Facilities using standard methods must maintain records of all interpretive decisions which they may make as a response to ambiguities in the methods or specifications contained in standards. Draft standards are to be managed as non-standard methods.

Note: Facilities should make all reasonable efforts to ensure that interpretations made are consistent with those of other facilities and regulatory authorities. The appropriate Standards Australia committee should be advised of any interpretive issues. Other facilities accredited for the same test should also be consulted. Attendance at relevant fora where such interpretations are discussed is strongly encouraged.

In some circumstances NATA may impose additional requirements on standard methods. This action is only taken where testing in accordance with the stated requirements of a standard is likely to cause an inappropriate interpretation of the results appearing in a report and thereby bring NATA into disrepute. Such a requirement would only remain in place until the standard was appropriately amended.

Where a standard does not adequately define the methods or contains ambiguities which would make it impossible to consistently apply the requirements, NATA may refuse accreditation.

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

Uncertainty of measurement is to be expressed as the expanded uncertainty having a specific coverage probability (often 95 %). The unit of the uncertainty shall always be the same as that of the property value or in a term relative to the property value, for example a percentage or ratio of the property value.

7.7 Measuring equipment

Facilities must ensure they comply with NATA's *Metrological Traceability* for all tests, measurements and calibrations that have a significant effect on reported values.

In-house calibrations

A facility performing its own calibrations will also be subject to technical assessment of these calibrations. The assessment team will determine if the in-house calibrations are fit for the purpose for which they are being used and that a reasonable estimate of the associated measurement uncertainty has been made. Where possible, the review of in-house calibrations will be covered as part of the measuring equipment aspects during reassessments. Where significant additional assessment time or additional assessors are required, there will be an additional and ongoing cost associated with this activity. Specialist calibration assessors will only be used when either the calibration is outside the area of expertise of the Technical Assessor(s) who would normally conduct the assessment of the RMP or if it would be more time or cost effective.

Note: Refer to NATA's *Equipment Assurance, In-house Calibration and Equipment Verification* for additional information.

Reference standards and equipment shall be calibrated over the range for which accreditation is held and to the appropriate level of accuracy specified in relevant methods.

7.8 Data integrity and evaluation

7.8.1 Whenever possible, a second staff member should check all calculations and data transfers. The identity of the second staff member checking the calculations and/or data transfers must be evident.

7.8.2 b) Problems may arise when computer files such as spreadsheets, word processor worksheets and/or report files are reused by overwriting previous results. Only blank templates should be used.

7.9 Metrological traceability of certified values

Certifying Authorities (CA)

NATA accredited facilities that have been appointed as Certifying Authorities (CA) by the National Measurement Institute (NMI) must also comply with the reporting requirements of NMI Legal Metrology. Such facilities should contact NMI to ensure that they are aware of current requirements relating to CA status.

Note: National Measurement Act

Where measurement traceability in accordance with Section 10 of the National Measurement Act 1960 is required, facilities performing such measurements must have Regulation 13 Certificates for their reference standards. Regulation 13 Certificates are issued by calibration facilities appointed as Verifying Authorities under the National Measurement Regulations. Further information can be obtained from the National Measurement Institute (NMI).

The National Measurement regulations contain schedules listing the maximum permissible variations and maximum permissible uncertainties that are required for various reference standards and measuring instruments.

7.12 Characterization

Facilities which perform their own reference value provision (Characterisation) and who are not accredited for these measurements under ISO/IEC 17025 are required to participate in appropriate Proficiency Testing (PT) activities.

Facilities are encouraged to participate in as broad a range of PT activities as practicable, but at least once every two years for each major area of measurement or related activity that contributes to the quality of the reference materials produced, where such programs are available.

Where formal PT programs are not available for any activities or do not provide sufficient coverage, facilities must investigate other means of assuring the quality and performance of the activities which contribute to the quality of the reference material.

Note: Refer to NATA's *Proficiency Testing* for further information.

7.13 Assignment of property values and their uncertainties

7.13.3 Producers shall have a system for reviewing and, where necessary, updating their uncertainty calculations following recalibration of reference equipment, a change of subcontractors, a change of material suppliers or other changes that would significantly affect the magnitude of relevant uncertainty components.

7.14 RM documents and labels

7.14.1 In instances where results not covered by the Scope of Accreditation are included in reports covering accredited activities, the notation *'NATA accreditation does not cover the performance of this service*', or similar wording, shall be applied.

Note: Refer to NATA's *Use of the NATA emblem, NATA endorsement and references to accreditation* for further information.

Preliminary reports (however named) may be issued when components of a certificate or documentation have not yet been completed. However, those results which are reported must be checked and authorised and the status of the report (for example 'preliminary') must be evident.

Where an accredited facility issues a preliminary report prior to the final report, the final report shall contain a reference to the preliminary report.

No report, whether preliminary or final, shall include results not authorised for release.

7.14.3 b) The facility shall not report on a Reference Material Certificate an uncertainty of property value which is less than or better than that stated in the its Scope of Accreditation.

Uncertainties of measurement shall be rounded up and be reported using a maximum of two significant figures. Uncertainties should be in the same units of the property value or expressed as a ratio or percentage of the property value.

A producer is not permitted to report on a Reference Material Certificate an uncertainty of property value which is less than or better than that stated in their scope.

7.16 Control of quality and technical records

7.16.2 All records must include the identity of the person making the record.

It is recognised that a number of staff may be involved in production. It is the facility's responsibility to identify the critical steps(s) in the process and ensure that the identities of the staff concerned are recorded.

The records system must include a copy of each product information sheet or certificate that contains work covered by the Scope of Accreditation, or must allow one to be reproduced, including details such as the endorsement (if applicable) and identification of the person who authorised the document.

In general, the records system must include the following:

- the RM identification;
- document identification;
- date of the document;
- the identity of test methods;
- the identity of test equipment;
- original observations and calculations;
- the identity of the person performing tests, measurements and calibrations;
- an indication that calculations and manual data transfers have been checked;

- any other information specified in the method, other contractual documents or relevant statutory regulations.

Rounding of results shall only be performed at the final stage of reporting, unless otherwise required by the method. Rounding should be made to the level of precision specified in the reporting requirements of the method.

7.16.7 Unless otherwise prescribed, retention times shall not be less than 4 years or, in the case of equipment records, the maximum recalibration interval of equipment (whichever is the longer period).

8 Management system requirements

8.1.1 General

The management system documentation must include or reference the Scope of Accreditation and the policy on the use of the NATA endorsement.

8.1.2 Option A

For commentary relating to adoption of Option A, refer to the individually referenced clauses below (8.6 and 8.7).

8.1.3 Option B

Certified ISO 9001 management system

An RMP facility seeking accreditation to ISO 17034 may exercise Option B (i.e. establish an ISO 9001 management system). In such cases, the system may not be assessed in full by NATA subject to:

i) the management system being certified by a certification body accredited by JAS-ANZ or by another signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA), and able to certify management system schemes to ISO 9001; and

ii) copies of the most recent certification audit reports being made available to NATA for review; and

iii) the management system demonstrates the fulfillment of the requirements of clauses 4 to 7 of ISO 17034; and

iv) the management system has established the following with regard to the facility's RMP activities:

- a quality policy;
- control of documents;
- control of records;
- management review;
- internal audits;
- considers and actions risks and opportunities;
- corrective action;
- improvement;
- customer feedback.

The required extent of assessment will depend on the evidence provided while ensuring that the certified management system addresses points iii) and iv). Where nonconformities are identified, these will be reported against clause 8.1.3.

Non-certified ISO 9001 management system

NATA will assess the management system in full against the requirements of Option A when the facility has adopted an ISO 9001 system which has not be independently certified by a certification body recognized under the IAF MLA.

8.6 Management reviews (Option A)

The effectiveness of the management system shall be reviewed by management at least once per year.

Note: Refer to the international document APLAC TC 003 *Management Review for Laboratories and Inspection Bodies* for additional information.

8.7 Internal Audits (Option A)

The internal audit schedule must cover, ideally within a twelve-month period, all of clauses 4 to 8 of ISO 17034.

Note: Refer to the international document APLAC TC 002 *Internal Audits for Laboratories and Inspection Bodies* for additional information.

Reference Material Producers Appendix A: Reference culture producers

This appendix details specific requirements for accreditation of reference culture producers under the following categories and subcategories of reference materials.

CATEGORY B BIOLOGICAL AND CLINICAL PROPERTIES

B7 Parasitology

B8 Bacteriology and mycology

B9 Virology

Producers of reference cultures are advised that a number of guidelines relating to procurement, preservation, maintenance and distribution of reference cultures are available from the World Federation for Culture Collections (www.wfcc.info) and the Common Access to Biological Resources and Information (www.cabri.org).

The clause numbers in this section follow those of ISO 17034 but since not all clauses require interpretation the numbering may not be consecutive.

6.3 Provision of equipment, services and supplies

6.3.2 Documented acceptance/rejection criteria must be available for new strains considered for the collection.

The facility must obtain all available information regarding the strain and origin of material being acquired from external organisations. The date of arrival, the depositor, the scientific name and the strain designation must be recorded. Further information to be considered should include the country of origin, name of isolator, date/time/geographic location of isolation, taxonomic identification (if known), phenotypic/genotypic strain properties, bibliographic references and known distribution restrictions.

6.3.3 The identity, viability, passages and purity of strains used in production must be confirmed. Refer to NATA's *Maintenance of Microbiological Reference Culture Collections (MRCC)* available on the NATA website.

7.12 Characterization

Including after preservation, the viability, purity and identity of the preserved strain must be confirmed.

7.14 RM documents and labels

Users of reference cultures must be provided with the conditions of resuscitation, preservation and storage e.g. media, time, temperature.

Instructions on opening ampoules, dehydration of (freeze-)dried cultures or other appropriate advice regarding management of the material must also be provided to users.

Strains that are potentially pathogenic to humans, animals or plants, or that produce toxic or hallucinogenic compounds, should be clearly labelled and secured in accordance with regulatory requirements.

Care must be taken to ensure that organisations requesting hazardous strains of microorganisms hold the necessary permits.

7.16 Control of quality and technical records

7.16.2 In addition to the records of identity, confirmation and maintenance on each strain held by the facility, the records must also include:

- the preservation procedures used;
- the optimal growth media and temperatures;
- any data on biochemical or other characteristics;
- regulatory conditions applying to the strain e.g. in relation to quarantine, containment levels, security and patent status.

Reference Material Producers Appendix B: Reference gas producers

This appendix details specific requirements for accreditation of reference gas producers under the following categories and subcategories of reference materials.

CATEGORY A CHEMICAL COMPOSITION

A7 Reference gases

A7.1 Reference gas mixtures

A7.3 Trace volatile organic compounds

Note: Accreditation to ISO/IEC 17025 for the characterisation of a gas mix is not appropriate when such a mix is to be used as reference material.

Certification of reference gas mixtures is based on two methods of characterisation:

1) Certified Reference Materials – produced according to ISO 6142.1:2015 *Gas analysis - Preparation of calibration gas mixtures - Part 1: Gravimetric method for Class I mixtures*;

Note: 'Certified Reference Material' is a primary type reference gas that can be produced using gravimetric techniques with analytical verification of the composition values in accordance with ISO 6142.1. Traceability for these types of gases is to the amount of substance contained within. A number of guidelines relating to the production, maintenance and distribution of reference gases are available in ISO 6142.1:2015 *Gas analysis - Preparation of calibration gas mixtures - Part 1: Gravimetric method for Class I mixtures.*

2) Certified Reference Materials – certified by analytical methods.

Note: In general, gas standards (sold mostly as calibration gases to testing facilities) are produced by decanting a series of pure gases into a cylinder to make a mixture. This production process can be done using a combination of hydrostatic (pressure) and gravimetric techniques. The decanted cylinder is tested using gas chromatography and gas analyser instruments/techniques for determining the assigned value. Instruments need to be calibrated using a certified reference gas, prior to performing characterisation steps.

The clause numbers in this section follow those of ISO 17034 but since not all clauses require interpretation the numbering may not be consecutive.

6.3 Provision of equipment, services and supplies

6.3.2 The constituents of gas mixtures must be reconfirmed if the mixtures have not been received from one of the following:

- a facility accredited to ISO 17034 by an accreditation body recognised by NATA under one of the regional mutual recognition arrangements (MRA) e.g. Asia Pacific Laboratory Accreditation Cooperation (APLAC) MRA;
- Australia's National Measurement Institute (NMI) or a national metrology institute that is a signatory to the Comité International des Poids et Mesures (CIPM) MRA.

Note: Refer to NATA's *Metrological Traceability*.

7.11 Assessment and monitoring of stability

7.11.2 A history of the assigned property values for different types of reference mixtures can be used to determine the stability of the gas mixture. The knowledge of previously determined measurements for specific gas mixtures and concentrations will assist in establishing long term and short term stability periods.

7.14 RM documents and labels

7.14.2 For each reference mixture held by the facility, the following details, as a minimum, must be available:

- constituents of the mixture;
- date produced;
- confirmation procedures used;
- regulatory conditions applying to the gas mixture and its storage.

Note: ISO 6141:2015 *Gas Analysis - Contents of Certificates for Calibration gas Mixtures* provides addition guidance on the contents of certificates.

Reference Material Producers Appendix C: Reference grain producers

This appendix details specific requirements for accreditation of reference grain producers under the following categories and sub-categories of reference materials.

CATEGORY A CHEMICAL COMPOSITION

A3 Organic reference materials

A3.2 Agricultural materials, fertilisers

A3.3 Foodstuffs

Proximate analysis

Nutritional properties

Vitamins

Other food additives

- antioxidants
- emulsifiers

Toxins

- animal origin
- plant origin
- other biological origin

Trace elements

Trace organics

- pesticide residues
- other organic contaminants

The accreditation of reference grains covers measuring, characterising and assigning values for protein content in wheat and barley (e.g. using the Dumas and Near-infrared (NIR) spectroscopic techniques). The addition of other types of grain materials will be considered on request. The Scope of Accreditation for the production of reference grains will include the following comments, as applicable, under the relevant sub-categories:

- Production of a certified reference material for total protein analysis in wheat and barley and assigning of a property value and associated uncertainty of measurement by Dumas combustion.
- Production of a certified reference material for total protein analysis in wheat and barley and assigning of a property value and associated uncertainty of measurement by NIR techniques.

The clause numbers in this section follow those of ISO 17034 but since not all clauses require interpretation the numbering may not be consecutive.

6.3 Provision of equipment, services and supplies

6.3.3 For NIR instrumentation, the facility must ensure information regarding the reference grains and/or control check samples used for checking the (daily) stability of the instrument is maintained.

6.3.4 Records of grain suppliers whose grain is used for collaborative studies must be maintained.

7.4 Material handling and storage

Samples should be stored dry in airtight containers when not in use, at ambient room temperature and away from direct sunlight.

7.16 Control of quality and technical records

7.16.2 For each batch of candidate and reference grain held by the facility, the following details, as a minimum, must be recorded:

- storage location;
- type of grain;
- quantity of grain;
- indicative value.

For reference grain, the following information must also be recorded:

- assigned value of grain, if possible;
- date produced;
- regulatory conditions applying to the grain e.g. in relation to quarantine, export, containment levels etc.

References

This section lists publications referenced in this document. The year of publication is not included as it is expected that only current versions of the references shall be used.

Standards

ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
ISO 6141	Gas Analysis - Contents of Certificates for Calibration gas Mixtures
ISO 6142.1	Gas analysis - Preparation of calibration gas mixtures - Part 1: Gravimetric method for Class I mixtures

NATA References

General NATA Document	*NATA Rules*
General Accreditation Criteria	*Proficiency testing*
General Accreditation Criteria	*Metrological traceability*
General Accreditation Criteria	*Equipment assurance, in-house calibration and equipment verification*

Other references

Regulation 13 Certificate - *A Regulation 13 certification (Verification of standards of measurement under the National Measurement Regulations 1999)*

Amendment Table

The table below provides a summary of changes made to the document with this issue.

Section	Amendment
Entire document	This document replaces the former Reference Material Producers ISO 17034 Standard Application Document. The document has been reviewed and updated to reflect the new accreditation criteria documentation structure.