General Accreditation Criteria

Reference Material Producers

ISO 17034 Standard Application Document

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Purpose

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

Facilities must comply with all documents in the relevant *NATA Accreditation Criteria* (NAC) package (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

6.2 Subcontracting

6.2.4 The following must 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 the ILAC 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 *General Accreditation Criteria: Metrological Traceability Policy* 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.

7.7 Measuring equipment

Facilities must ensure they comply with NATA's *General Accreditation Criteria: Metrological Traceability Policy* 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 technical 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 *General Accreditation Criteria: 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 should 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.

7.12 Characterisation

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 *General Accreditation Criteria*: *Proficiency Testing Policy* 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.

For Certified Reference Material Producers

The Scope of Accreditation must identify materials produced and reported as Certified Reference Materials (CRMs).

The Scope of Accreditation is to be expressed in terms of a Provision of a Certified Reference Value Capability which will include the facility's estimate of their uncertainty of measurement (U_{CRM}) capability across the range of each property value they report. The Reference Value in this sense being the provision of a property value and its uncertainty of measurement, which is then used as a Reference Standard by the material consumer. Producers are required to maintain detailed records for these estimates and to review them periodically for currency.

The text '*with Provision of a Certified Reference Value Capability of* -'will accompany each capability statement listed in the Scope of Accreditation.

CRMs that are an identification value (such as species identification) or where the property value is an ordinal number (such as a colour fastness chart) do not require an uncertainty of measurement to be stated in the Scope of Accreditation.

The evaluation of the measurement uncertainty must include all quantities that might contribute significantly to the uncertainty of the property value. Where Producers incorporate several techniques and/or methods within the one material category, the Producer will determine which of these are considered the major techniques and/or methods to be included in the Scope of Accreditation to suitably inform the users of the CRM as to the best capability of the Producer. The level of detail in the Scope of Accreditation will form part of the NATA assessment.

Note: For the definition of a measurement model and definitions of U_{CRM}, u_{sts}, u_{its}, & u_{bb}, refer to the clause covering Evaluating Measurement Uncertainty (Section 6.1) of ISO Guide 35.

Where practicable the measurement model will include contributions applicable to a best typical batch production and include contributions from short term stability (as dispatched to the customer u_{sts}), long term stability (at the time of sale u_{its}) and homogeneity (between bottle variation u_{bb}). These batch dependent contributions may be based on ideal conditions as applicable for each material type.

The uncertainty of property values from single-artefact CRMs that are certified based on a single calibration may be carried out using the normal procedures as outlined in ISO/IEC Guide 98-3 (the GUM). It should be noted, however, that the uncertainty calculation of this type of CRM must also include long term stability effects.

Note: An example of this type of CRM would be a hardness block.

In instances where an external testing laboratory is engaged to provide major contributions to the uncertainty budget (u_{sts}, u_{its} and u_{bb}) the Producer must provide evidence of their assessment of the laboratory's technical competence including the claimed traceability and evaluation of the measurement uncertainty of these contributions. Where an external laboratory provides a reference value determination/characterisation or provides testing as part of material preparation, the requirements for measurement traceability, in the first instance for a calibration, and the second for a test, as applicable in NATA's *General Accreditation Criteria: Metrology Traceability Policy* must be applied with records kept by the Producer. These records will form part of the assessment of the Scope of Accreditation.

Producers will be expected to be able to provide evidence that they can provide CRM property values to customers with measurement uncertainties equal to those covered by the Reference Value Capability in their Scope of Accreditation. Such evidence would typically include performance in proficiency testing, measurement audits and/or rigorous evaluation of the U_{CRM} during assessment.

There shall be no ambiguity on the expression of the Reference Value Capability on the Scopes of Accreditation and, consequently, on the smallest uncertainty of property value that can be expected to be achieved by a Producer. Particular care should be taken when the property value covers a range of values. This is generally achieved through employing one or more of the following methods for expression of the uncertainty:

- a single value or ratio (e.g. % of Certified Value), which is valid throughout the property value range;
- a range. In this case a Producer should state the assumption/s to be used for the interpolation required to find the uncertainty at intermediate values;
- an explicit function of the property value;
- open intervals (e.g., "$U < x$") are not allowed in the specification of uncertainties;
- a matrix of measurement points where the values of the uncertainty depend on the property value and additional parameters.

When the property value is dependent on associated values such as a range of temperature, hydration or dilution, the associated value range must also be stated. In this instance a matrix of measurement points is a useful form of expressing the Reference Value Capability.

The uncertainty covered by the Reference Value Capability shall 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.

Producers shall have a system for reviewing and, where necessary, updating their uncertainty calculations following recalibration of reference equipment, a change of

external testing laboratories, 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 *General Accreditation Criteria: 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 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.

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 several 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 been independently certified by a certification body recognised 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.

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.

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 17034 *General requirements for the competence of reference material producers*

ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*

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

ISO/IEC Guide 98-3	*Uncertainty of measurement - Part 3: Guide to the expression of uncertainty of measurement*
ISO Guide 35	*Reference materials — Guidance for characterization and assessment of homogeneity and stability*

Amendment table

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

Section or Clause	Amendment
7.9	Metrological traceability of certified values - Certifying Authorities (CA) has been removed as it is no longer required
7.13.3	Re-instated the instructions for Certified Reference Materials scope of accreditation expression in terms of a provision of a Certified reference Value Capability.
	Removal of appendices B and C. Removal of appendix A into an as it is already a separate annex.