



APLAC GUIDANCE ON REFERENCE MATERIAL USE AND PRODUCTION

PURPOSE

Reference Materials (RMs) are used in all stages of the measurement process, for method validation, calibration and quality control. They are used for assessing laboratory proficiency through interlaboratory comparisons and are a source of metrological traceability.

This document prepared for use by Accreditation Bodies (ABs) gives guidance on the use of reference materials in test, measurement and inspection and application of ISO 17034:2016 for accreditation of producers of reference materials. Section 1 contains a brief history of TC 008 and the application of accreditation of ISO 17034:2016 for accreditation of RMPs at ILAC and APLAC. Section 2 provides a short summary of the principles of metrological traceability derived from reference materials, the use of reference materials and provides reference to the ISO Guides and Standard that support reference materials. Section 3 provides the principles for accreditation of Reference Material Producers (RMPs) acknowledging the distinction between measurement results of a material obtained from a testing laboratory to a RM property value provided by an RMP. Section 4 provides guidance for the assessment of RMPs. Section 5 provides guidance on the interpretation of the requirements listed in ISO 17034:2016 and Section 6 acknowledges the set of minimum requirements for Scopes of Accreditation for RMs as detailed in ISO/IEC 17011:2017.

It is acknowledged that Certified Reference Materials (CRMs) are a specific type of RM, with the guidance in the document applicable to all types of RMs unless specifically mentioned the otherwise.

AUTHORSHIP

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1. BACKGROUND

Since 2004 ILAC has passed a number of resolutions concerning the accreditation of Reference Material Producers, beginning with resolution GA 8.11 which acknowledges the assessment of technical competence of reference materials producers as accreditation of a conformity assessment activity, and resolution GA 8.12, that these accreditations will be conducted against harmonized criteria based on ISO Guide 34 and ISO/IEC 17025 in combination. ILAC Resolution GA 9.28 stated an intention to add RMP accreditation to the ILAC Mutual Recognition Arrangement (MRA) when 'appropriate procedures for this activity are developed'. Then in 2009 when ISO Guide 34 was updated and included a reference to ISO 15189 as well as ISO/IEC 17025, ILAC Resolution GA 16.20 rescinded the 'Guide 34 and 17025 in combination' requirement acknowledging accreditation of RMPs may be applied to Guide 34 alone.

At the twentieth general assembly meeting in November 2016, ILAC passed resolution GA 20.13 endorsing the recommendation to extend the ILAC MRA to include accreditation of RMPs to the specific criteria of ISO 17034 and start accepting applications for recognition as soon as the applicable peer evaluation documents are updated.

A full listing of the ILAC resolutions may be found on the ILAC website www.ilac.org

In 2005 APLAC inaugurated a MRA for RMP accreditation based on ISO Guide 34 and a set of additional accreditation criteria produced by the APLAC Technical Committee, these additional criteria are the origin of this technical document. TC 008 was further revised when ISO Guide 34 was updated in 2009 and then again in 2013 to acknowledge the resolution made by ILAC GA 16.20 in 2012.

With the publication of ISO 17034 *General Requirements for the competence of reference material producers* in 2016 a number of fundamental changes were implemented:

- inclusion of requirements for production of all types of reference materials, and additional specified requirements for certified reference materials;
- harmonization with the revisions of ISO Guide 30, ISO Guide 31 and ISO Guide 35;
- inclusion of more details on required reference material documentation;
- inclusion of risks and opportunities;
- restructuring based on the common structure adopted by other International Standards on conformity assessment developed by *ISO Committee on Conformity Assessment (CASCO)*;
- incorporation of modifications based on ISO/CASCO PROC 33.

Unlike ISO Guide 34, the ISO guide for RM certificates and accompanying documentation (Guide 31) and the guide for characterization and assessment of homogeneity and stability (Guide 35) are now *informative* references in ISO 17034. An additional informative reference specific to the establishment and expression of metrological traceability ISO/TR 16476 has been added. The only *normative* reference in ISO 17034 is ISO/IEC 17025, though in the introduction to ISO 17034 it states for tests performed in the medical field, ISO 15189 can be used as the

reference instead of ISO/IEC 17025. All terms are as defined in the newest revisions of ISO Guide 30, VIM, and ISO 9000.

This issue of TC 008 has been heavily revised from the previous version. This revision is informed by discussions held at the APLAC workshop on Reference Materials and Proficiency Testing conducted in November 2016, during which it was decided to:

- incorporate and give consideration to the changes made in ISO 17034;
- to remove additional requirements which have been intentionally removed from ISO 17034 or are now better defined and explained in the ISO standard;
- to expand the scope of TC 008 by providing guidance on the use of reference materials by all accredited facilities, not just the accreditation of reference material producers;
- to provide reference to publications that support reference materials which have been published or updated since the previous issue, such as, the ISO Guide on good practice in using reference materials (Guide 33), ISO Guide 35, ISO/TR 16476, etc. and;
- where possible, replace additional requirements previously stated in TC 008 with a reference to the equivalent requirement already contained in other publications, such as, the latest revision of ISO/IEC 17011 (scopes of accreditation) or APLAC MR-001 (use of the accreditation symbol).

2. REFERENCE MATERIALS AND METROLOGICAL TRACEABILITY

“reference material, RM

material, sufficiently homogeneous 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

Note 1 to entry: RM is a generic term.

Note 2 to entry: Properties can be quantitative or qualitative, e.g. identity of substances or species.

Note 3 to entry: Users may include calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.

Note 4 to entry: ISO/IEC Guide 99:2007 has an analogous definition (5.13), but restricts the term ‘measurement’ to apply to quantitative values. However Note 3 of ISO/IEC Guide 99:2007, 5.13 (VIM), specifically includes qualitative properties, called ‘nominal properties’.”

ISO Guide 30 clause 2.1.1

“certified reference material, CRM

Reference material (RM) characterized by a metrologically valid procedure for one or more specified properties, accompanied by an RM certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability

Note 1 to entry: The concept of value includes a nominal property or a qualitative attribute such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities or levels of confidence.

Note 2 to entry: Metrologically valid procedures for the production and certification of RMs are given in, among others, ISO Guides 34 and 35.

Note 3 to entry: ISO Guide 31 gives guidance on the contents of RM certificates.

Note 4 to entry: ISO/IEC Guide 99:2007 has an analogous definition (5.14).”

ISO Guide 30 clause 2.1.2

ISO Guide 30 provides terms and definitions used in connection with reference materials and their corresponding product information sheets, reports and certificates. The definitions of RMs and CRMs (collectively (C)RMs) above were developed by the ISO committee responsible for guidance on reference materials (REMCO) to incorporate the concepts of both quantitative and qualitative analysis. As these definitions differ from that currently contained in ISO/IEC Guide 99:2007 and JCGM 200:2008, it remains a future goal to harmonize these definitions in subsequent editions of these guides.

For users of reference materials, ISO Guide 31 informs the producers of RMs to use the term 'reference material certificate' solely for CRMs and the term 'product information sheet' is used for a document accompanying any other type of RM, thus making the distinction between RMs and RMs that are certified (CRMs). ISO Guide 31 is an informative reference in ISO 17034.

“Reference materials, in particular when certified (CRM), are a major tool for assuring the quality and reliability of results obtained in measurement and testing. CRM property values, in particular used for assessing the trueness of a measurement procedure as implemented in a laboratory, also establish traceability of the measurement result. Which reference the property values assigned to (C)RM should be traceable to, and how this traceability should be established, demonstrated, and reported on certificates is, therefore, a question of primary importance, mainly for RM producers. However, users of (C)RMs should also know what the endpoint of their traceability chain is, in particular for all purposes of cross-border acceptance of measurement results.”

ISO/TR 16476

ISO/TR 16476 has been developed by ISO/REMCO as a useful tool that investigates, discusses and specifies the general principles of establishing traceability of measurement results. The principles put forward are based on the joint BIPM, OIML, ILAC and ISO Declaration on Metrological Traceability (OIML Bulletin, Volume LIII, Number 1, January 2012). While ISO/TR 16476 is specifically an informative reference for establishing metrological traceability of certified values (clause 7.9 of ISO 17034) the principles put forward on metrological traceability are applicable to all measurement and testing making ISO/TR 16476 a useful reference not only for RMPs but all users of (C)RMs as well.

ISO Guide 35 supports implementation of ISO 17034 by providing more specific guidance on technical issues related to the production of (C)RMs. This guide explains the concepts for processes such as the assessment of homogeneity, stability, characterization, evaluation of uncertainty, and establishment of traceability for the certification of RMs.

Both ISO/TR 16476 and ISO Guide 35 share a common principle for metrological traceability, stating the traceability of a measurement result consists of two parts. To clearly define the identity of the property value and then, establish the traceability of this property value to the stated reference. The principle of metrological traceability is the same for producers of RMs and the users of (C)RMs such as test and measurement laboratories. Thus a certificate supporting a Certified Reference Material will always clearly identify the stated reference to which the certified property value is traceable.

ISO Guide 33 describes good practice in the use of (C)RMs in a measurement process. The recommendations it provides are exemplified by real-world examples, which to some degree also reflects the level of complexity associated with RMs. Property values may be traceable to international scales (such as SI) or other established measurement standards. A measured property can be defined without reference to a particular measurement procedure or is operationally defined to which only results obtained by the same procedure can be compared. Topics discussed include the handling of RMs, assessment of precision and bias, calibration, assignment of values, conventional scales, selection and use of RMs, etc. and is recommended as a reference for all users of (C)RMs.

3. PRINCIPLES OF ACCREDITATION AND REFERENCE MATERIALS

As detailed in ISO 17034, the production of reference materials involves a number of processes including:

- production planning^{*};
- the selection of subcontractors (where relevant)^{*};
- production control;
- material handling, storage and processing;
- assessment of homogeneity and stability;
- characterization and measurement of property values;
- assignment of property values and associated uncertainties^{*};
- authorization of property values and associated uncertainties^{*};
- authorization of RM documents^{*};
- distribution.

With all of these processes forming part of an ISO 17034 accreditation.

^{*} Processes that may not be subcontracted as per ISO 17034.

A RMP accredited to ISO 17034 may subcontract all but five of these processes as indicated above. A RMP may also be a testing and/or calibration provider holding both ISO 17034 and ISO/IEC 17025 accreditation, having a number of the RMP production processes such as characterization and assessment of homogeneity and stability assessed as part of their ISO/IEC 17025 accreditation. Where a commercial RMP is not accredited to ISO 17034 but is accredited to ISO/IEC 17025 for test and measurement activities that support the production of a RM, it is acknowledged these activities alone are not equivalent to all of the processes involved in the production and reporting of an (C)RM.

ISO/IEC 17011 provides clear distinction of the different types of conformity assessment activities (tests, calibration, inspection, certification, RMPs, proficiency testing providers, amongst others) to which a Conformity Assessment Body (CAB) may be accredited. ISO/IEC 17011 ensures use of an accreditation symbol will provide clear indication as to which conformity assessment activity an accreditation is related. The APLAC MRA is based on and makes distinct between each of the conformity assessment types in APLAC MR 001.

Thus under the MRA, each Accreditation Body is obliged to ensure certificates of accreditation contain a clear indication as to which conformity assessment type a CAB is accredited, giving consideration to instances where a facility who is a commercial RMP may only be accredited to ISO/IEC 17025 but not to ISO 17034.

Additionally, under the MRA, each Accreditation Body is obliged to ensure the use of their accreditation symbol gives clear indication as to which conformity assessment activity the accreditation is related, giving consideration to instances where a CAB may issue a 'Certificate of Analysis' of a material under a ISO/IEC 17025 accreditation, ensuring said certificate does not imply Reference Material Certification.

By following these obligations under the MRA, Accreditation Bodies will help avoid market confusion amongst the users of RMs when selecting an appropriate (C)RM based on documentation that may accompany a material.

4. PERFORMING THE ASSESSMENT OF A REFERENCE MATERIAL PRODUCER

Assessment preparation

Prior to conducting the on-site assessment, the AB will need to obtain sufficient information from the RMP to ensure all aspects of ISO 17034 are assessed in full. In addition to the usual information required from all accredited facilities (scope of accreditation, test methods, equipment, organization structure etc.), specific information required for the assessment RMPs includes:

- tasks performed for each type or group of RM products (characterization, homogeneity and stability testing) and methods/techniques used. This applies to all tasks whether performed in-house or subcontracted;
- subcontractor information, the tasks the subcontractors perform and relevant background information for each subcontractor for example, whether they are accredited for the activity and/or how the subcontractor has been deemed technically competent to perform the task.
- For CRMs, the stated reference for each CRM type or group, plus any other relevant information regarding metrological traceability including in-house calibrations.

As per the requirements in ISO/IEC 17011 clause 7.4, selection of a suitable assessment team is to be based on the activities performed by the RMP and their subcontractors, the scope of (C)RMs produced and technical disciplines covered.

Note: Further details on the preparation for assessment are found in ISO/IEC 17011.

Assessment of RMPs

During assessment, the AB is advised to pay particular attention to measurement procedures, metrological traceability, measuring equipment and how the RMP has ensured the quality of measurements that contribute to the property of (C)RMs produced, for example participation in proficiency testing activities.

ISO 17034 clause 7.6 requires measurement procedures meet the relevant requirements of ISO/IEC 17025 in order to ensure measurements made achieve the required specifications and accuracy of the RM property values. To achieve this requirement the AB will need to consider:

- the methods are appropriate (to the intended use) and are the latest edition unless it is not appropriate or possible to do so;
- in-house developed non-standard methods are developed by qualified personnel with adequate resources;
- non-standard methods include a clear specification to the requirements and be validated appropriately before use;
- non-standard methods, including in-house methods and methods used outside of their intended scope are validated to confirm they are fit for the intended use. The validation is as extensive as is necessary and a statement as to whether the method is fit for the intended use made, and;
- the range and accuracy of values obtainable from methods is relevant to the intended use.

Measuring equipment (ISO 17034 clause 7.7) used in RM production must also be used in compliance with relevant requirements of ISO/IEC 17025. To achieve this requirement, the AB should consider at least the following:

- the RMP and/or its subcontractors are furnished with the measuring and test equipment required. The equipment is fit for purpose and has been verified as complying with specified requirements;
- when the measurement accuracy and measurement uncertainty affect the validity of a RM property value, measuring equipment is calibrated;

Consequently the requirements for metrological traceability may apply to measuring equipment including equipment used in the production of non-certified RMs. See ISO/IEC 17025 for further details on the requirements for measuring equipment.

Note: ILAC Policy on the Traceability of Measurement Results, ILAC P10, may also be applied to other conformity assessment activities where testing and/or calibration are involved.

Proficiency testing can be used to monitor the on-going competence of the producer and subcontractors for all tests and measurements that contribute to the quality of an RM and its property value. During assessment the AB will need to consider that the requirements in ISO/IEC 17025 for assuring the quality of results are followed for all measurement procedures.

Note: ILAC Policy for Participation in Proficiency Testing Activities, ILAC P9, contains additional information on the use of proficiency testing in the accreditation process.

Assessment of RMP's Subcontractors

It should be emphasized that accreditation is granted to the RMP, and not to subcontractors and thus the AB will need to consider whilst at assessment documentation issued to subcontractors as a result of a successful assessment by the RMP and that said documentation does not imply certification nor accreditation by the AB. ISO/IEC 17011 contains additional requirements on the use of accreditation symbols and other claims of accreditation.

For critical activities undertaken by subcontractors, the AB should, where necessary, witness a selection of examples of how the RMP evaluates the competence of its subcontractors on-site, see clause 6.2.6 of ISO 17034. This may be necessary where the competence of the subcontractor involved in the generation of measurement data for the characterization of property values and assessment of homogeneity and stability cannot be determined through the information provided by the RMP.

It is noted, ISO 17034 prevents the selection of subcontractors as a subcontracted activity.

5. GUIDANCE ON THE APPLICATION OF ISO 17034:2016

This section provides guidance for the interpretation and application of ISO 17034. The title of each subsection is the same as the corresponding clause contained in ISO 17034 and as not all clauses require additional guidance, not all clauses have been listed.

4 General requirements

4.1 Contractual matters

- 4.1.1 When ensuring the requirements for a RM is adequately defined, documented and understood, the RMP will need to consider that the matrix, property values and the value's metrological traceability and measurement uncertainty meet the needs of the given application or field of application. In some cases, the stability time required should also be included in the review. If necessary, the RMP should give advice to the customers and help them to determine their needs.

4.2 Impartiality

No additional guidance.

4.3 Confidentiality

No additional guidance.

5 Structural requirements

No additional guidance.

6 Resource requirements

6.1 Personnel

No additional guidance.

6.2 Subcontracting

No additional guidance.

6.3 Provision of equipment, services and supplies

No additional guidance.

6.4 Facilities and environmental conditions

No additional guidance.

7 Technical and production requirements

7.1 General requirements

No additional guidance.

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- 7.2 Production planning
- 7.2.3 It is understood that pilot studies may sometimes need to be carried out and the need of any pilot study should be considered at the planning stage.
- 7.3 Production control
No additional guidance.
- 7.4 Material handling and storage
No additional guidance.
- 7.5 Material processing
When candidate RMs are sent to subcontractors for testing, they should be uniquely labeled, suitably packed and stored in suitable conditions during transport. Instructions on the storage conditions should be given to the subcontractors
- 7.6 Measurement procedures
The applicable requirements of ISO/IEC 17025 apply to measurement procedures. See Section 4, assessment of RMPs for additional guidance on application of the requirements of ISO/IEC 17025 for measurement procedures.
- 7.7 Measuring equipment
The applicable requirements of ISO/IEC 17025 apply to measuring equipment. See Section 4, assessment of RMPs for additional guidance on application of the requirements of ISO/IEC 17025 for measuring equipment.
- 7.8 Data integrity and evaluation
No additional guidance.
- 7.9 Metrological traceability of certified values
Additional guidance on reference materials and metrological traceability is provided in Section 2 of this document.
It should be noted that ILAC Policy on the Traceability of Measurement Results, ILAC P10, may also be applied to other conformity assessment activities where testing and/or calibration are involved.
- 7.10 Assessment of homogeneity
- 7.10.3 It should be noted that the requirements for measurement procedures in clause 7.6 also apply to the assessment of homogeneity.
- 7.11 Assessment and monitoring of stability
- 7.11.1 Prediction of stability using a model is acceptable if such model is well established and widely accepted in the discipline concerned.

It is noted, the requirements for measurement procedures in clause 7.6 also apply to the assessment of stability.

7.11.2 Under normal circumstances, stability assessment for each and every property value should be performed. It is not appropriate to assume the stability of a property value based on the assessment of another value unless correlation is demonstrated.

7.11.3 A change of procedure, or the source of the candidate materials, or a deviation from previous data may necessitate a reassessment of stability.

7.12 Characterization

7.12.3 When a property value is method-specific or operationally defined, only results using the same method are meaningful. Therefore to be more useful, methods published by standard writing bodies or widely recognized professional bodies in the concerned field are recommended.

7.12.4 It is noted, the requirements for measurement procedures in clause 7.6 also apply to the characterization of assigned property values.

7.13 Assignment of property values and their uncertainties

7.13.5 The uncertainty of property values from single-artifact CRMs that are certified based on a single calibration may be carried out using the normal procedures as outlined in the GUM. It should be noted, however, that the uncertainty calculation of this type of CRM will need to include long term stability effects.

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

It is necessary to have a system for reviewing and updating 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.

7.13.6 Uncertainty in this Section covers both “measurement uncertainty” of a quantity value and “uncertainty” associated with a nominal property (i.e. property of a phenomenon, body, or substance, where the property has no magnitude e.g. color chart, DNA sequence, etc.).

7.14 RM documents and labels

7.14.3 There are reference cultures kept in various economies such as American Type Culture Collection (ATCC), Type Culture Collection of Chinese Academy of Science (CGMCC), National Collection of Type Cultures (NCTC), UK, and European Collection of Animal Cell Cultures. Additionally, traditional biochemical tests and culturing techniques are used to define the identity of microorganisms and/or DNA sequencing may also be used. The traceability statement for these CRMs will need to identify which reference cultures, or which definition (measurement procedure), is referenced as the stated reference. Where the stated reference is a reference culture, it may be appropriate to also state the number of passages and the sub-culturing techniques on the certificate.

For some biological CRMs, both the DNA sequence as well as the identity of the microorganism is given on the certificate in which case it is necessary to clearly identify the certified property value, i.e. whether it is the identity or the DNA sequence or both.

Where the property value is operationally defined, it is necessary to clearly state the measurement procedure including the measurement unit, or the measurement standard. This is applicable for biological CRMs used for matching the test results (such as DNA sequence or serological / biochemical tests) with that of the test specimens, in which case the test (DNA sequence or serological / biochemical tests) used to characterize the microorganisms as well as the test results would be reported on the certificate.

For those CRMs where the identity of a chemical compound is the certified property value it may be warranted to report both the identity and the purity of the compound and, if applicable, other information such as its molecular structure, the confirmatory technique(s) used to identify the compound, the stated reference and the criteria for identity confirmation. A state reference and the criteria for identity confirmation are needed for supporting traceability for such qualitative CRMs.

7.15 Distribution service

No additional guidance.

7.16 Control of quality and technical records

No additional guidance.

7.17 Management of non-conforming work

7.17.1 Common examples of non-conforming work include environmental conditions in the testing or calibration areas exceeding the specified limits, tests performed using instruments with overdue calibration, acceptance criteria of quality control not met, unsatisfactory performance in proficiency testing schemes, etc.

It is important to note the need to keep records of non-conforming work in accordance with ISO 17034 clause 7.16.2 as these might be needed in a future dispute situation.

7.18 Complaints

No additional guidance.

8 Management system requirements

8.1 Options

No additional guidance.

8.2 Quality policy (Option A)

No additional guidance.

8.3 General management system documentation (Option A)

The management system of a RMP need not be complex. Its format will depend on a number of factors including the size of the RMP, number of staff members and the range, volume and complexity of the work it performs. In cases where a RMP is part of a larger organization, RMP activities may already be incorporated in a document covering the organization's total range of operations.

8.4 Control of management system documents (Option A)

No additional guidance.

8.5 Control of records (Option A)

Requirements for control of quality and technical records are also given in section 7.16 of ISO 17034.

8.6 Management review (Option A)

Additional guidance on management review is given in APLAC TC 003.

8.7 Internal audits (Option A)

8.7.1 RMP should perform internal audits at least once a year. The frequency may be adjusted depending on the demonstrable effectiveness of the management system and its proven stability.

8.7.2 Internal auditors should be familiar with the requirements of ISO 17034 and ISO/IEC 17025 (or ISO 15189 for medical RMs).

8.7.3 Additional guidance on internal audits is given in APLAC TC 002.

8.8 Actions to address risks and opportunities (Option A)

No additional guidance.

8.9 Corrective actions (Option A)

No additional guidance.

8.10 Improvement (Option A)

No additional guidance.

8.11 Feedback to customers (Option A)

No additional guidance.

6. DESCRIBING THE SCOPE OF ACCREDITATION FOR A REFERENCE MATERIAL PRODUCER

With a revision of ISO/IEC 17011 in 2017, a minimum set of requirements have been added when identifying a scope of accreditation for each of the conformity assessment types covered by this standard.

In the requirements provided for reference material producers, a scope of accreditation is to make distinction between certified RMs, non-certified RMs, or both when listing the specific types of RMs covered by the accreditation.

For all conformity assessment types, ISO/IEC 17011 recognizes the use of flexible scopes of accreditation noting additional procedural requirements for Accreditation Bodies when assessing and managing flexible scopes. Accreditors of RMPs are advised the more flexible a scope of accreditation, the more effort will be required during preparation and assessment of the RMP as the RMP will have to determine and demonstrate that the measurement procedures used remain valid across the breath of material matrix, analyte/characteristic presented in the scope.

To ensure consistency across Accreditation Bodies, members of the MRA are reminded to comply with the minimum requirements for scopes of accreditation as described in ISO/IEC 17011 and give consideration to any additional guidance developed by ILAC in future revisions of ILAC G18.

7. REFERENCES

- ISO Guide 30 Reference materials - Selected terms and definitions
- ISO Guide 31 Reference materials - Contents of certificates, labels and accompanying documentation
- ISO Guide 33 Reference materials - Good practice in using reference materials
- ISO 17034 General requirements for the competence of reference material producers
- ISO Guide 35 Reference materials - Guidance for the characterization and assessment of homogeneity and stability
- ISO/TR 16476 Reference materials - Establishing and expressing metrological traceability of quantity values assigned to reference materials
- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
- ISO 15189 Medical laboratories - Requirements for quality and competence
- ISO/IEC 17011 Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies
- ISO/IEC Guide 98-3:2008 (GUM)
Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement
- ISO/IEC Guide 99 (VIM, JCGM 200:2012)
International vocabulary of metrology - Basic and general concepts and associated terms.
- OIML Bulletin, Volume LIII, Number 1, January 2012
Joint BIPM, OIML, ILAC and ISO Declaration on Metrological Traceability
- ILAC P10 ILAC Policy on Traceability of Measurement Results
- ILAC G18 Guidelines for the formulation of scopes of accreditation for laboratories
- APLAC MR 001 Procedures for establishing and maintaining the APLAC mutual recognition arrangement amongst accreditation bodies
- APLAC TC 002 Internal Audits for Laboratories and Inspection Bodies
- APLAC TC 003 Management Review for Laboratories and. Inspection Bodies
- ISO Guide 80 Guidance for the in-house preparation of quality control materials (QCMs)