

APAC Guidance for accreditation of Reference Material Producers (RMPs)

**Issue No. 2.1**

**Issue Date 26 June 2025**

**Application Date 26 June 2025**

**AUTHORSHIP**

This document was produced by the APAC Technical Committee 1 (Laboratories, Inspection Bodies, Reference Materials Producers, Proficiency Testing and Biobanks).

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1. INTRODUCTION

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 can be a source of metrological traceability.

2. SCOPE

2.1 This document has been prepared for use by accreditation bodies (ABs) applying ISO 17034:2016 for accreditation of producers of reference materials.

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

3. REFERENCE standards and guides

3.1 ISO Guide 30 (under revision as ISO 33400 Reference materials - Vocabulary) provides terms and definitions used in connection with reference materials and their corresponding product information sheets, certificates and reports. The definitions of RMs and CRMs were developed by the ISO committee responsible for publications on reference materials ISO TC334 to incorporate the concepts of both quantitative and qualitative analysis. As these definitions differ from those currently contained in ISO/IEC Guide 99 (VIM) and JCGM 200, it remains a future goal to harmonize these definitions in subsequent editions of these guides.

3.2 ISO/TR 10989 Reference materials - Guidance on, and keywords used for, RM categorization, reports on existing classification and categorization schemes, describes the principles and the layout of a harmonized scheme, and contains a comprehensive list of keywords recommended for RM categorization.

3.3 ISO 33401 is intended to help reference material producers in preparing clear and concise documentation to accompany a reference material. To help prevent market confusion, RM documents that do not contain Certified Values should avoid the use of ‘Certificate’ in the title.. ISO 33401 replaces ISO Guide 31 which is an informative reference in ISO 17034.

3.4 ISO 33405 supports the implementation of ISO 17034 by providing more specific guidance on technical issues related to the production of (C)RMs. This standard explains the concepts for processes for the assessment of homogeneity, stability, characterization, evaluation of uncertainty, and establishment of traceability for the certification of RMs. ISO 33405 replaces ISO Guide 35 which is an informative reference in ISO 17034.

3.5 ISO 33405 states 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 calibration laboratories. Thus, a certificate supporting a Certified Reference Material will always clearly identify the stated reference to which the certified property value is traceable.

3.6 ISO 33406 provides guidance on the implementation of ISO 17034 in the production of RMs having one or more assigned qualitative property values, for expressing uncertainties for qualitative property values, and for establishing traceability of qualitative properties.

3.7 ISO 33407 notes the requirements of ISO 17034 and provides specific guidance on technical considerations to produce pure organic substance certified reference materials (CRMs) that are used by laboratories to calibrate measurement equipment, and procedures to establish metrological traceability of the respective results. The guidance is relevant only to CRMs comprising organic compounds whose structures are specifically defined, where polymeric materials are not included.

3.8 ISO 33403 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. This document is recommended as a reference for all users of (C)RMs.

4. PRINCIPLES OF ACCREDITATION AND REFERENCE MATERIALS

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

1. production planning\*;
2. the selection of subcontractors (where relevant)\*;
3. production control;
4. material handling, storage and processing;
5. assessment of homogeneity and stability;
6. characterization of property values;
7. assignment of property values and associated uncertainties\*;
8. authorization of property values and associated uncertainties\*;
9. authorization of RM documents\*;
10. distribution.

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

*\* Processes that are not to be subcontracted as per ISO 17034.*

4.2 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.

4.3 Where a commercial RMP is not accredited to ISO 17034 but is accredited to ISO/IEC 17025 for test and calibration activities that support the production of a RM, it is acknowledged that these activities alone are not equivalent to all of the processes involved in the production and reporting of a (C)RM.

4.4 Thus it is the responsibility of each Accreditation Body to ensure the use of their accreditation symbol gives clear indication as to which conformity assessment activity the accreditation is related. Where a CAB issues a ‘Certificate/Report of Analysis’ of a material under an ISO/IEC 17025 accreditation, it must be ensured that said certificate does not give the impression that it is being issued under a Reference Material Producers accreditation.

4.5 Reference Material Producers (RMPs) often engage in the practice of supplying reference materials (RMs) that are then marketed or distributed under the branding of another organization. These arrangements, commonly referred to as "rebranding" or "OEM (Original Equipment Manufacturer) models," can present challenges with respect to conformity to ISO 17034 and the correct application of accreditation symbols under ILAC P8.

5. PERFORMING THE ASSESSMENT OF A REFERENCE MATERIAL PRODUCER

Assessment preparation

5.1 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.), the following information for the assessment RMPs should be considered:

1. tasks performed for each type or group of RMs (characterization, homogeneity and stability testing) and methods/techniques used. This applies to all tasks whether performed in-house or subcontracted;
2. 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;
3. the stated reference for each CRM type or group, plus any other relevant information regarding metrological traceability including in-house calibrations.

5.2 As per the requirements in ISO/IEC 17011 clause 7.4, the 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

5.3 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:

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

5.4 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:

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

5.5 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.

5.6 Proficiency testing can be used to support method validation, claims of measurement capability, and 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

5.7 It should be emphasized that accreditation is granted to the RMP, and not to subcontractors. The AB will need to ensure that any documentation issued to subcontractors by a RMP as a result of a successful assessment by the RMP of the subcontractor, does not imply certification nor accreditation by the AB. ISO/IEC 17011 and ILAC P8 detail requirements for the use of accreditation symbols and other claims of accreditation.

5.8 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 a 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.

5.9 ISO 17034 prevents the selection of subcontractors as a subcontracted activity.

Assessment of OEM/Rebranded RMs

5.10 The AB should assess the controls implemented by the RMP to manage OEM or rebranding arrangements, including any contractual agreements, documentation approvals, and labeling controls. The AB should be satisfied that:

1. The accredited RMP maintains oversight and control over the RM documentation;
2. The end-user is not misled about the producer of the RM or the accreditation status of the organization branding the material;
3. Traceability and batch documentation link each rebranded material clearly and unambiguously to the accredited RMP;
4. The accreditation symbol is not used on rebranded or OEM RM documentation.

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

6.1 In accordance with ISO/IEC 17011:2017, a scope of accreditation must make the distinction between certified RMs, non-certified RMs when listing the specific types of RMs covered by the accreditation.

6.2 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. Accreditation Bodies using flexible scopes of accreditation must ensure that the RMP has determined and can demonstrate that the measurement procedures used remain valid across the breadth of material matrices, analyte/characteristic covered by the scope.

6.3 Consideration should be given to additional guidance developed by ILAC in ILAC G18.

6.4 Guidance on and key words used for reference materials categorization can be found in ISO/TR 10989.

7. REFERENCES

ISO Guide 30 Reference materials - Selected terms and definitions

ISO 33401 Reference materials - Contents of certificates, labels and accompanying documentation

ISO 33403 Guidance for the use of reference materials

ISO 33405 Reference materials - Approaches for characterization and assessment of homogeneity and stability

ISO 33406 Approaches for the production of reference materials with qualitative properties

ISO 33407 Guidance for the production of pure organic substance certified reference materials

ISO/TR 10989 Reference materials - Guidance on and keywords used for. RM categorization

ISO 17034 General requirements for the competence of reference material producers

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 P8 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Conformity Assessment Bodies

ILAC P9 ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing

ILAC P10 ILAC Policy on Metrological Traceability of Measurement Results

ILAC G18 Guideline for describing Scopes of Accreditation

APAC MRA-001 Procedures for Establishing and Maintaining Mutual Recognition Amongst APAC Accreditation Bodies

APAC MRA-002 APAC Mutual Recognition Arrangement (MRA)

8. AMENDMENT TABLE

This table provides a summary of the changes to the document with this issue.

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| **Date** | **Section(s)** | **Amendment(s)** |
| 2025-06-26 | All | Updated taking into account revision of existing and new publications produced by ISO TC334 |
| 2025-06-26 | 3 | Removed reference to ISO/TR 16476. |
| 2025-06-26 | 3 | Added reference to ISO/TR 10989. |
| 2025-06-26 | 5 | Add guidance for assessing the practice of rebranded RMs by a third party |
| 2025-06-26 | 6 | Removed section providing a summary of interpretation of the clauses of ISO 17034. Much of the information provided is now available in the revised and new ISO 334 publications. |
| 2021-12-10 | All sections | General editorial update and consolidation of guidance into a more concise guide. |
| 2019 | Background | This section removed |
| 2019 | Introduction | Section titles ‘Purpose’ in the previous version split into ‘Introduction’ and ‘Scope’ to align with the structure of other APAC guides. |