



**APLAC REQUIREMENTS FOR AND GUIDANCE ON THE ACCREDITATION
OF A REFERENCE MATERIAL PRODUCER AND THE RESULTING SCOPE
OF ACCREDITATION**

PURPOSE

The requirements and guidance in this document have been developed to ensure a more uniform approach to the assessments of reference material producers, and the resulting scope of accreditation. Since this document contains both requirements and guidance, only those statements that include “shall” are requirements.

AUTHORSHIP

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1. BACKGROUND

In October 2004, the ILAC General Assembly passed a resolution identifying the general approach that Accreditation Bodies (ABs) shall take when assessing and accrediting reference material producers (RMPs). Below are the ILAC GA resolutions relating to RMP accreditation.

ILAC Resolution GA 8.11

The General Assembly acknowledges that assessing the technical competence of bodies producing reference materials with assigned values is accreditation of a conformity assessment activity.

ILAC Resolution GA 8.12

The General Assembly resolves that accreditation of technically competent bodies producing reference materials with assigned values will be conducted against harmonized criteria on ISO Guide 34 and ISO/IEC 17025 in combination.

ILAC Resolution GA 9.28

Following 2004 ILAC GA resolutions 8.11 and 8.12 relating to accreditation of Reference Materials Producers, the General Assembly resolves that the accreditation to ISO Guide 34 in combination with ISO/IEC 17025 be included under the current ILAC arrangement when appropriate procedures for this activity are developed and agreed by ILAC.

In 2005, the APLAC MRA Council resolved (MRA RES 15.22) that “the inaugural signing of the extended APLAC MRA take place once 4 accreditation bodies have been evaluated and have met all the conditions for the extension of their scopes of recognition to include RM producers”.

The inaugural signing of the APLAC MRA for RMP accreditation took place on 7 December 2007 in Kuala Lumpur, Malaysia. The four inaugural signatories are A2LA, NATA, CNAS and IAJapan. It is acknowledged that there are other APLAC MRA signatories that are keen to implement RMP accreditation programs. However, the operations of RMPs can vary over time and in relation to the (C)RMs produced. Questions have been raised about the appropriate ways to approach an assessment that presents such a complexity of activities, and also how to define the resulting scope of accreditation.

The APLAC MRA Council asked the APLAC Technical Committee to address the complexities and activities associated with the assessment and accreditation of a RMP. Issue 1 of this document was intended to serve that purpose. Subsequently, it was recognized that some guidance given in issue 1 of this document was essential for the harmonized and consistent application of the accreditation criteria. Therefore this document was reviewed with a view to identify those points which should be considered as mandatory. It should, however, be stressed that no additional accreditation requirements are imposed on the RMPs. The accreditation criteria remain as ISO Guide 34 and ISO/IEC 17025 in combination. This document only serves as an application document for the accreditation criteria. It may, however, include some requirements for

the assessment procedures, the presentation of the scope of accreditation and supplementary criteria arising from the APLAC MRA. To maintain its usefulness, guidance has been retained in the document.

This document has taken into account the experience gained in the assessment and accreditation of RMPs by some APLAC members. The outcome from an APLAC workshop on the accreditation of RMPs, held in Tsukuba, Japan in 2007, have also been included. A conclusion that this workshop drew is that, depending on the actual situation of the RMP and the RMs it produced, general guidelines or principles for the application of ISO/IEC 17025 that are relevant to the activities of RMP tasks are more useful than specific guidelines. Specific guidelines may lead to rigidity and hamper the exercise of professional judgment. This might undermine the assessment of competence. Examples of the application are useful. Hence, it is not the intention of this document to give specific guidelines.

The ILAC resolution directed the use of ISO Guide 34 and ISO/IEC 17025 in combination to accredit RMPs. It should be noted that ISO Guides 30, 31 and 35 and the VIM are cross-referenced in ISO Guide 34 as normative documents, and compliance with these standards is also mandatory for the accreditation of RMPs.

A gap analysis table between ISO Guide 34:2000 and ISO/IEC 17025:2005 is provided in Annex 1.

A cross reference between ISO/IEC 17025:2005 and ISO Guide 34:2000 is provided in Annex 2.

The value of accreditation to ISO Guide 34 and the application of the accreditation requirements in ISO Guide 31 are to ensure that appropriate information is available in the certificates of any (C)RM purchased for the purpose of conducting method validation, ensuring metrological traceability of measurement results, and/or instrument calibration. Lack of this information will impact the accuracy and validity of test and calibration results. The APLAC MRA for accreditation of RMPs should enable regulators and users to purchase reference materials from competent and appropriately accredited RMP facilities.

2. INTRODUCTION

The following principles apply to the assessment and accreditation of RMPs.

2.1 The RMP shall be the body that is subject to accreditation. The RMP can be considered a “producer” or a “facility” but cannot be considered solely a “laboratory”. The production of (C)RMs involves some activities that are not normally considered the activities of a laboratory. The term “production” used in this document includes all necessary activities and tasks leading to a (C)RM supplied to customers, and includes at least those given in the table in Section 2.5. In other words, production is not restricted to just the manufacture and preparation of the candidate material. Where an organisation only provides services such as provision of reference values to a candidate RM, it cannot be considered as a RMP.

2.2 The accreditation criteria shall be ISO Guide 34 and ISO/IEC 17025 in combination. A RMP shall meet all the requirements of these two documents that are relevant to its activities, before accreditation is granted. ISO Guide 34 is applicable to all activities of RMP, including testing, calibration and measurement. The relevance of a requirement given in ISO Guide 34 and ISO/IEC 17025 should be assessed in the context of the activities performed rather than the organisational structure of the RMP facility.

2.3 An RMP may choose or require the use of subcontractors to perform various tasks leading to the production of its (C)RMs, and its role may change in relation to the (C)RM produced. In this regard, the APLAC MRA Council (MRA RES. 18.14) resolved “that, within the context of the APLAC MRA for accreditation of reference material producers (RMPs), an accredited RMP is an organisation that assigns the property values and determines the associated uncertainties (ISO Guide 34:2000, clause 5.15) and issues the certificate (ISO Guide 34:2000, clause 5.16); that accredited RMPs shall be competent to perform those tasks that cannot be outsourced to sub-contractors or other outside parties.” When subcontractors are used for the preparation of the materials and for other activities, the RMP shall take responsibility for ensuring that these tasks are performed in a competent manner and that the relevant requirements for the use of subcontractors, given in ISO Guide 34 and ISO/IEC 17025, are met.

2.4 The RMP shall retain information within its management system that clearly details the roles of, and its relationships with, subcontractors and other related parties.

2.5 The following table provides examples of how tasks involved in RM production may be undertaken by the RMP and its subcontractors. This table is offered for the purpose of description and should not be considered to provide exhaustive coverage of all possible RMP/subcontractor arrangements. The ISO document(s) listed in the second column are considered to contain requirements that are relevant to the respective tasks listed in the first column.

Stages/ Tasks of (C)RM production	Relevant ISO Documents	Responsible organisations							
		Type 1	Type 2	Type 3	Type 4	Type 5	Type 6	Type 7	Type 8
<i>Production planning</i>	ISO Guide 34 + ISO/IEC 17025	R	R	R	R	R	R	R	R
# Material preparation**	ISO Guide 34 + ISO/IEC 17025	R	S	S	S	S	R	S	R
# Homogeneity/ Stability testing	ISO Guide 34 + ISO/IEC 17025	R	R	R	S*	S*	S*	S*	R
# Characterization of Property Values	ISO Guide 34 + ISO/IEC 17025	R	R	R	S*	S*	S*	R	S*
<i>Assignment of and decision on Property Values</i>	ISO Guide 34 + ISO/IEC 17025	R	R	R	R	R	R	R	R
<i>Authorization of property values and issue of certificate</i>	ISO Guide 34	R	R	R	R	R	R	R	R
# Handling and storage (including post certification testing)	ISO Guide 34 + ISO/IEC 17025	R	R	S	R	S	S	S	R
Distribution & post distribution service	ISO Guide 34	R	R	S	R	S	R	S	R

Tasks denoted by *italics* shall be performed by the RMP

R = Tasks performed by the RMP

S = Task performed by subcontractor

If performed by a subcontractor, the RMP shall ensure the technical competence of that subcontractor

* Any conclusions in regards to these tasks shall be made by the RMP.

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

2.6 The following are some possible modes of operation of an RMP.

- a) A single organisation produces the candidate (C)RM and assigns the property values based on its own measurement results (type 1 as given in the above table).
- b) An organisation produces the candidate (C)RM and assigns the property values based on the measurement results from other (subcontractor) laboratories. Handling and storage of the (C)RM are performed by the subcontractor. The certificate is issued by the producer (type 6).
- c) An organisation produces the candidate (C)RM and is responsible for the homogeneity and stability studies, for example. The property values are characterized by a NMI or an external accredited laboratory. The producer sells the (C)RM (type 8).
- d) An organisation subcontracts the preparation of a candidate reference material and then assigns the property values based on measurement results from its own laboratories. The organization that issues the certificate sells the (C)RM (type 2).
- e) An organisation subcontracts the production of a candidate reference material and all laboratory work necessary to assign the (C)RM property values. The certificate is issued by the RMP and the RM is distributed by the RMP or an external party (type 5).

3. PERFORMING THE ASSESSMENT OF A REFERENCE MATERIAL PRODUCER

- 3.1 The accreditation body (AB) should, based on the modes of operation and the activities performed by the applicant RMP, determine the most applicable combination of accreditation criteria. The accreditation criteria (ISO standards) given in the table in Section 2.5 shall be the base criteria used.
- 3.2 An AB should also investigate available technical standards that might be included to support accreditation for discipline-specific RM programs to underpin the technical rigour of the discipline specific program (e.g. ISO 6141:Requirements for certificates for calibration gases and gas mixtures; ISO 6142:Gas analysis-Preparation of calibration gas mixtures – Gravimetric method.) The scope of accreditation may refer to these technical standards when they are used by the RMP.
- 3.3 It should be noted that a RMP may operate in different modes at different times and/or for different (C)RMs. This shall be taken into account in the assessment approach that is adopted.
- 3.4 The AB shall obtain information from the RMP that demonstrates how the RMP is organised and how it meets the relevant requirements of ISO Guide 34 and ISO/IEC 17025. The information should include but not be limited to the following.
- (i) The type or categories of RMs that are produced by the RMP.
 - (ii) The technical standards that are used for the production of RMs.
 - (iii) The tasks/activities performed by the RMP in relation to specific RMs.
 - (iv) If the RMP uses a subcontractor for RM production processes, the following information is required;
 - name and address of the subcontractor,
 - the scope of tasks/activities performed by the subcontractor,
 - the type of testing, calibration and measurement activities done by the subcontractor,
 - evidence of the technical/quality credibility of the subcontractor (e.g. certification to ISO 9001 for non-testing activities and/or accreditation to ISO/IEC 17025 for testing, calibration and measurement activities).
 - (v) Any plans to have separate ISO/IEC 17025 accreditation for the testing/calibration/measurements determinations, if the RMP does them.
- 3.5 The applicability of ISO Guide 34 and ISO/IEC 17025 requirements to the operation of RMPs should be considered on a case by case basis because they may vary with the actual situation of the RMP and the RMs they produce, and they

may also change as the production process changes. The AB should perform an analysis of the RMP operation and determine how the two criteria documents should be applied, based on the principles, guidance and requirements given in this document.

- 3.6 Assessment with respect to the RMP's compliance with ISO/IEC 17025 requirements for testing/calibration/measurement determinations activities should be given special attention.

A RMP facility may be considered as an organization whose business is the production (and certification) of (C)RMs where testing, calibration and measurement activities are undertaken. Even if all of testing, calibration and measurement activities are carried out by outside parties, an RMP facility would still performing some activities related to measurements such as "review of requests, tenders and contracts", "subcontracting of tests and calibrations", "selection of methods", "estimation of uncertainty of measurement", "control of data", "sampling", "handling of test and calibration items", etc.

- 3.7 All requirements of ISO/IEC 17025 may be applicable to testing, calibration and measurement activities of the RMP. Testing, calibration and measurement activities include not just performance of tests, calibrations, measurements, and sampling, but also other related activities such as review of requests, tenders and contracts, subcontracting of tests and calibrations, selection of methods, validation of methods, measurement traceability, assuring the quality of test and calibration results, etc. The requirements of ISO/IEC 17025 are not applicable to activities of the RMP other than testing, calibrations and measurement and other related activities. The requirements that are given in ISO Guide 34 and ISO/IEC 17025 are applicable to other activities (i.e. activities not related to testing, calibration and measurement) of the RMP. There should not be inconsistent requirements but only more specific requirements given in ISO/IEC 17025 for activities related to testing, calibration and measurement. Some of the more important clauses of ISO/IEC 17025 that are related to RMP tasks are listed in Annex 3. Nevertheless, all requirements need to be considered for each of the RMP tasks.
- 3.8 If the RMP or the specified subcontractor is accredited to ISO/IEC 17025 by an APLAC and/or ILAC MRA signatory for the testing/calibration/measurement activities it undertakes in the production of RMs, this accreditation can be considered satisfactory to meet the ISO/IEC 17025 requirements for testing or calibration competency, as required by the RMP accreditation criteria.
- 3.9 If the RMP is not accredited to ISO/IEC 17025, but performs the testing/calibration/measurement determinations activities, the AB's assessment of the RMP shall include an assessment of the RMP's testing/calibration/measurement determinations activities against the relevant parts of ISO/IEC 17025.
- 3.10 During the RMP assessment, the AB shall assess how the RMP determines the competency of the subcontractor(s) that performs the testing/calibration or

measurement activities for it, if the external subcontractor is not accredited to ISO/IEC 17025.

3.11 Because the RMP has overall responsibility for the competent performance of all RMP tasks, and for ensuring the suitability of assigned RM values and resulting (C)RM certificates/statements, the AB's assessors shall give the following activities covered by ISO/IEC 17025 particular attention during the assessment of the RMP, whether they are performed in house or by a subcontractor:

- a) Selection of test or calibration methods should be done in conjunction with sections 5.10, 5.14 and 5.15 of ISO Guide 34. The degree of rigour of the RMP's processes for analytical method development and validation should be strong, and the assessors should include a robust assessment of metrological traceability and measurement uncertainty estimation, in line with the scrutiny given to a calibration laboratory.
- b) Measurement uncertainty estimations for the testing/ calibration and measurement processes shall be appropriately rigorous and properly verified, because these estimations will affect the final (C)RM assigned values and their associated uncertainties.
- c) When establishment of metrological traceability through a clear pathway to the SI cannot be established, certified reference materials shall be used wherever possible. The uncertainties in the certified values of the (C)RM used shall be suitable for establishing metrological traceability appropriate to the RMs being produced.
- d) Proficiency testing can be used to monitor the on-going competence of the testing and calibration processes. When the RMP performs testing/calibration or measurement that significantly affects the validity and uncertainty of the assigned property value of a RM, the RMP shall participate in the proficiency testing programs as required in ILAC P9 for the tests/calibrations and measurements it performs. When an accredited laboratory acts as a subcontractor, it shall also participate in proficiency testing programs, as required to meet ILAC P9 for the tests and calibrations it performs. A non-accredited subcontractor shall similarly demonstrate competence through proficiency testing or other equivalent means. When proficiency testing programs are not available, other means to demonstrate competence, e.g. use of measurement audits and check samples, should be considered.
- e) Though accreditation to ISO/IEC 17025 for testing/calibration and measurement activities is the most direct way to demonstrate technical competence, sometimes accreditation is not relevant or practical, e.g. when it is a very specialised and non-routine measurement, or the subcontractor is a research facility that is used infrequently, or the subcontractor is used only once. In such cases, the RMP shall monitor the competence of these subcontractors in other ways such as provision of a method protocol with a rigorous quality control regime, and/or through proficiency testing (also see

3.11 d) above). Otherwise, other means of determination of property values shall be used, e.g. by a collaborative study involving multiple laboratories (see clause 9.4.2 of ISO Guide 35:2006).

3.12 The AB shall establish an appropriate assessment team and generate an appropriate agenda to cover the full breadth of the RMP's activities. This includes adequately trained technical assessors who have relevant knowledge of the categories of (C)RMs produced and an ability to cover the technical competency elements of an assessment based on ISO/IEC 17025, if relevant, in addition to ISO Guide 34.

3.13 The AB shall ensure that the assessment process establishes how the RMP determines the competence of its subcontractors to undertake the tasks they have been allocated in the production of each type of (C)RM. For critical activities, the AB shall, where necessary, witness a selection of examples of how the RMP evaluates the competence of its subcontractors on-site. This will be necessary where the competency of the subcontractor involved in the generation of measurement data for the characterisation of property values cannot be determined through the information provided by the RMP. It may also be necessary for the generation of other measurement data used by the RMP (such as for homogeneity and/or stability testing), depending on the criticality of the data to the integrity of the (C)RMs produced.

3.14 An on-site assessment of the subcontractor by the RMP is not normally needed if the testing or calibration subcontractor is accredited for the specific test or calibration, and the degree of the review done by the RMP of the contract with its subcontractor is appropriate and at a minimum includes a review of:

- a) the measurand required,
- b) the test and/or calibration method(s) used,
- c) the required measurement uncertainty,
- d) metrological traceability,
- e) the reporting requirements,
- f) the performance of proficiency testing activities (where suitable and applicable); and
- g) attention by the subcontractor to performing the work with the required technical rigour.

Note: The contracting referred to above is between the RMP and its subcontractors, and not between the RMP and its customers. As such, it relates to clauses 4.5 and 5.2.2, in addition to clause 4.4.3, of ISO Guide 34:2000.

3.15 When the testing or calibration subcontractor is not accredited, the same issues should be addressed, but an on-site assessment by the RMP may be needed (see Section 3.13).

3.16 When the testing or calibration tasks are performed by the RMP, clause 4.1.4 of ISO/IEC 17025 that covers conflict of interest shall be applied when assessing the

in-house testing or calibration function and its relationship with the production department.

- 3.17 Sampling, sub sampling and sample size taken for production and testing are critical in the assignment of property values as well as homogeneity and stability testing. These shall be carefully assessed by the AB's assessors.
- 3.18 The resulting (C)RM certificates/statements shall be rigorously assessed by the assessment team. An RMP is not a laboratory and should not be required to meet the ISO/IEC 17025 requirements for reporting of results (i.e. clause 5.10); instead (C)RM certificates shall meet ISO Guide 31 requirements.
- 3.19 ISO Guide 34 requires (C)RM certificates to meet all of the *requirements* of ISO Guide 31, noting that ISO Guide 31 has many "should" statements that are not requirements; however these "shoulds" may be considered on a case by case basis as additional requirements where they are fundamental to the application and technical validity of the (C)RM.
- 3.20 If the AB is not satisfied with the competency examination of its subcontractors (especially non-accredited subcontractors) done by the RMP, the AB could arrange to visit those subcontractors or could deny accreditation of the RMP until the RMP can provide objective evidence of a satisfactory competency evaluation.

Note: It is recommended that a visits to a subcontractor is done in the presence of the RMP, and with the consent of the RMP and the subcontractor concerned.

Examples of unsatisfactory findings may include, but not be limited to:

- a. The RMP did not do a second party audit of the subcontractor;
 - b. The RMP audit did not cover the subcontractor's tasks;
 - c. The subcontractor did not respond to the RMP's findings and/or the RMP did not follow up on the audit finding resolutions;
 - d. Non-conformities found by the AB's assessment team during the assessment support the concern that an adequate competency examination of the subcontractor was not done; and/or
 - e. No participation or inappropriate participation in PT activities or unsatisfactory investigation of outlying results from PT by the subcontractors.
- 3.21 The AB should have arrangements with its accredited RMPs to notify the AB of any changes in the arrangements between the RMP and its subcontractors during the accreditation period. Upon such notification the AB shall properly assess the new subcontractor arrangements in order to determine whether accreditation requirements continue to be met.

**4. DESCRIBING THE SCOPE OF ACCREDITATION FOR A REFERENCE
MATERIAL PRODUCER**

- 4.1 An AB shall provide a scope of accreditation that describes the specific types of CRMs and RMs that the RMP is competent to produce. Although RMP accreditation conveys competency as a producer, not as a laboratory, testing and/or calibration are integral components of RM production. As such, the scope of accreditation, or other records/reports, if necessary, shall also describe the specific activities, including those tests, calibrations and measurements, and possibly those tasks given in first column of the table in Section 2.5, for which the RMP is accredited. The scope shall include the range of property values for the (C)RMs with the associated uncertainties, where relevant, for which the RMP is accredited.
- 4.2 Categories and sub-categories of reference materials are given in Appendix B of ILAC G12 and this appendix can serve as good guidance to describe the specific types of (C)RMs for which a RMP is accredited. Sub-categories may be required and can be included for clarity in the RMP's scope of accreditation. This information could be useful to the customers of the RMP.
- 4.3 The scope and certificate of accreditation shall state that the RMP meets the requirements of ISO Guide 34. There are relevant ISO/IEC 17025 requirements pertaining to every RMP assessment process, even if the RMP is only doing the tasks of production planning, assigning property values and issuing the certificate (e.g. sections 5.4.1, 5.4.2 and 5.4.6 of ISO/IEC 17025:2005). A reference to ISO/IEC 17025 may, therefore, also be included in each RMP's scope of accreditation for ISO Guide 34, i.e. the RMP meets the applicable requirements of ISO/IEC 17025 for the production of (C)RMs.
- 4.4 If the RMP requests accreditation as a laboratory to ISO/IEC 17025 for its testing, calibration or measurement activities, this accreditation can be expressed in a separate scope and certificate of accreditation. In this case, all the criteria for laboratory accreditation apply.
- 4.5 As an RMP can do various tasks (refer to Section 2.5), accreditation shall be granted to it for those activities that has been assessed and found to meet the relevant requirements. The scope of accreditation, or other records/reports that support the scope, shall clearly state these activities, together with the (C)RM(s) that the RMP is accredited to produce. If a RMP does certain activities that are outside the scope of its accreditation, it shall not claim that it is accredited for producing the (C)RM concerned, and cannot use an endorsed certificate/statement for such a (C)RM.

Annex 1: Gap Analysis Between ISO GUIDE 34 AND ISO/IEC 17025
(Informative)

ISO Guide 34:2000	ISO/IEC 17025:2005	Remarks
1 Scope	1. Scope	The scope of ISO Guide 34 is specific for reference material producers.
2 Normative references	2. Normative references	In ISO Guide 34 reference is made to several other ISO Guides specific for reference material producers
3 Terms and definitions	3. Terms and definitions	In ISO Guide 34 specific definitions are given for 'reference material producer' and 'collaborator'
4 Organisation and management requirements		
4.1 Quality system requirements		
4.1.1 General	4.2.1	In addition to ISO/IEC 17025, ISO Guide 34 requires the reference material producer to describe the procedure for establishing the quality of materials as a component of the quality system.
4.1.2 Quality policy	4.2.2	In addition to ISO/IEC 17025, ISO Guide 34 requires <u>e.g.</u> that the quality policy also refers to ISO Guides 30, 31 and 35.
4.1.3 Quality system	4.2.1, 4.2.6	
4.1.3.a)	nil	This requirement is specific for reference materials and not covered by ISO/IEC 17025. Arrangements for the suitable choice of candidate reference materials are required
4.1.3.b)	nil	This requirement is specific for reference materials and not covered by ISO/IEC 17025. Preparation procedures are required.

ISO Guide 34:2000	ISO/IEC 17025:2005	Remarks
4.1.3.c)	nil	This requirement is specific for reference materials and not covered by ISO/IEC 17025. The QS should cover the achievement of required degree of homogeneity.
4.1.3.d)	nil	This requirement is specific for reference materials and not covered by ISO/IEC 17025. Assessment of the stability of the reference material is required.
4.1.3.e)	nil	This requirement is specific for reference materials and not covered by ISO/IEC 17025. Procedures for undertaking characterization are required.
4.1.3.f)	5.6	ISO Guide 34 requires <u>practical</u> realization of traceability to (inter)national standards of measurement
4.1.3.g)	nil	This requirement is specific for reference materials and not covered by ISO/IEC 17025. Assignment of property values is required and reference to ISO Guide 31 is made.
4.1.3.h)	5.6.3.4, 5.8.1	
4.1.3.i)	5.8.1, 5.8.2	
4.1.3.j)	nil	This requirement is not covered by ISO/IEC 17025. Compliance with ISO Guides 30, 31, 34 and 35 is required.
4.2 Organization and management		
4.2.1	4.1.1	
4.2.2	4.1.2 and 4.1.3	
4.2.3.a)	4.1.5.a)	
4.2.3.b)	4.1.5.b)	
4.2.3.c)	4.1.5.c)	
4.2.3.d)	4.1.5.d)	
4.2.3.e)	4.1.5.e)	
4.2.3.f)	4.1.5.f)	
4.2.3.g)	4.1.5.h)	
4.2.3.h)	4.1.5.i)	

ISO Guide 34:2000	ISO/IEC 17025:2005	Remarks
4.2.3.i)	4.1.5.j)	
4.3 Document and information control		
4.3.1 General	4.3.1	
4.3.2 Document approval and issue		
4.3.2.1	4.3.2.1	
4.3.2.2	4.3.2.2	
4.3.3 Document changes		
4.3.3.1	4.3.3.1	
4.3.3.2	4.3.3.2	
4.3.3.3	4.3.3.3	
4.3.3.4	4.3.3.4	
4.4 Request, tender and contract reviews		
4.4.1	4.4.1	
4.4.2	4.4.2	
4.4.3	4.4.3	
4.5 Use of collaborators		
4.5.1	4.5.1	ISO Guide 34 requires procedures for the production of reference materials. ISO/IEC 17025 requires full compliance to the requirements of ISO/IEC 17025 for subcontractors.
4.5.2	4.5.1	
4.5.3	4.5.4	
4.6 Procurement of services and supplies		
4.6.1	4.6.1	
4.6.2	4.6.2	
4.6.3	4.6.2	The requirement of ISO Guide 34 clause 4.6.3 is specific in case of no formal approval of the quality of service.
4.6.4	4.6.2	
4.6.5	4.6.4	In addition to ISO/IEC 17025, ISO Guide 34 requires that the records include any quality assurance approval that is held by the suppliers and/or collaborators.
4.7 Client feedback	4,7.2, 4.8	

ISO Guide 34:2000	ISO/IEC 17025:2005	Remarks
4.8 Control of non-conforming (poor quality) reference materials		
4.8.1	4.9.1	
4.8.1.a)	4.9.1.a)	
4.8.1.b)	4.9.1.a)	
4.8.1.c)	4.9.1.b)	
4.8.1.d)	4.9.1 a)	
4.8.1.e)	4.9.1.c)	
4.8.1.f)	4.9.1.d)	
4.8.1.g)	4.9.1.e)	
4.8.2	4.9.2	
4.9 Corrective action		
4.9.1 General	4.11.1, 4.11.3	In addition to ISO/IEC 17025, ISO Guide 34 requires to document and implement any changes to operational procedures resulting from corrective action investigations.
4.9.2 cause analysis	4.11.2	
4.9.3 Corrective actions	4.11.3	
4.9.4 Monitoring of corrective action	4.11.4	
4.9.5 Result	4.15.1	
4.10 Preventive action		
4.10.1	4.12.1	In addition to ISO/IEC 17025, ISO Guide 34 requires to review all operational procedures in a systematic way at regular intervals.
4.10.2	4.12.2	
4.10.3	4.15.1	
4.11 Records		
4.11.1 General		
4.11.1.1	4.13.1.1, 4.13.2.1	ISO Guide 34 requires that reference material producers should record information that might be needed in future dispute situation.
4.11.1.2	4.13.1.2	
4.11.1.3	4.13.1.3	
4.11.1.4	4.13.1.4	
4.11.2 Records and reports	4.13.2.1, 5.10.1	
4.12 Internal audits		
4.12.1	4.14.1	

ISO Guide 34:2000	ISO/IEC 17025:2005	Remarks
4.12.2	4.14.2	
4.12.3	4.14.3	ISO Guide 34 requires the corrective action discharged within an agreed timescale.
4.13 Management reviews		
4.13.1	4.15.1	
4.13.2	4.15.2	
5 Technical and production requirements		
5.1 Management, staffing and training		
5.1.1	5.2.1, 5.2.4, 4.1.5.h)	This ISO Guide 34 requirement is more specific with regard to the organisation and managerial staff (including technically competent manager).
5.1.2	5.2.1	
5.1.3	5.2.2	
5.1.4	5.2.5	
5.2 Collaborators		
5.2.1	4.5.1	This requirement is specific for reference materials and not fully covered by ISO/IEC 17025. It concerns requirements for collaborators participating on an interlaboratory basis for the purpose of the production or characterization of a reference material.
5.2.2	4.5.4	This requirement is specific for reference materials and not fully covered by ISO/IEC 17025.
5.3 Production planning		
5.3.1	nil	This requirement is specific for production of reference materials and not covered by ISO/IEC 17025.
5.3.2	nil	This requirement is specific for reference materials and not covered by ISO/IEC 17025.
5.3.3.a till 5.3.3.n	nil	These requirements are specific for reference materials and not covered by ISO/IEC 17025.
5.4 Production control	nil	

ISO Guide 34:2000	ISO/IEC 17025:2005	Remarks
5.5 Environment		
5.5.1	5.3.1, 5.3.2	This ISO Guide 34 requirement is more specific with regard to the different environmental conditions involved.
5.5.2	5.3.1	This requirement is specific for reference materials. The reference material producer must ensure that any collaborator involved also meets environmental conditions.
5.5.3	5.3.2	
5.5.4	nil	This requirement is specific for reference materials and not covered by ISO/IEC 17025. It concerns the implementation of appropriate health, safety and environmental protection precautions.
5.6 Material handling and storage		
5.6.1	5.8.1	This requirement of ISO Guide 34 is more specific for reference materials.
5.6.2	5.8.4	This requirement is specific for reference materials and not fully covered by ISO/IEC 17025. It concerns the adequate packaging of all reference materials.
5.6.3	nil	This requirement is specific for reference materials and not covered by ISO/IEC 17025. It concerns the assessment of the condition of all stored/stocked items and materials throughout storage life.
5.6.4	nil	This requirement is specific for reference materials and not covered by ISO/IEC 17025. It concerns the control of packing and marking processes to ensure conformity with safety and transport requirements.

ISO Guide 34:2000	ISO/IEC 17025:2005	Remarks
5.6.5	nil	This requirement is specific for reference materials and not covered by ISO/IEC 17025. It concerns the labelling of the reference materials.
5.6.6	nil	This requirement is specific for reference materials and not covered by ISO/IEC 17025. It concerns the making of arrangements to ensure the integrity of each reference material throughout the entire production process.
5.7 Post-distribution service		
5.7.1	5.5.7, 4.9.1.d), 4.11.1	This ISO Guide 34 requirement is more specific for reference materials.
5.7.2	nil	This requirement is specific for reference materials and not covered by ISO/IEC 17025. The producer should provide an advisory service to offer guidance (including complaint procedure) and technical services to users.
5.8 Material preparation		
5.8.1.a till 5.8.1.h	nil	
5.8.2	nil	
5.9 Assessment of homogeneity and stability		
5.9.1	nil	
5.9.2	nil	
5.9.3	nil	
5.9.4	nil	
5.9.5	nil	
5.10 Measurement methods		
5.10.1	5.4.1	
5.10.2	5.4.4 5.4.5.2	This ISO Guide 34 requirement is for the authorization of in-house developed methods.
5.10.3	5.7.1	

ISO Guide 34:2000	ISO/IEC 17025:2005	Remarks
5.11 Measuring equipment		
5.11.1	5.5.2, 5.5.10	The requirement of ISO Guide 34 is only for measuring equipment.
5.11.2	5.5.7	The requirement of ISO Guide 34 is only for measuring equipment.
5.11.3	5.5.8	The requirement of ISO Guide 34 is only for measurement standard and reference equipment.
5.11.4	5.6.1	
5.11.5	5.6.2.1.1	
5.12 Traceability and validation		
5.12.1	5.6.2.1.1, 5.6.2.2.1	
5.12.2	5.6.2.1.2, 5.6.2.2.2	
5.13 Data evaluation		
5.13.1	5.4.7.1	
5.13.2	5.4.7.2, 4.13.1.4	The requirement of ISO Guide 34 5.13.2.d) is more specific.
5.13.3	4.13.2.1	
5.14 Characterization		
5.14.a till 5.14.d	nil	These requirements are specific for reference materials and are not covered by ISO/IEC 17025. Where possible, the characterization should comply with the requirements of ISO Guide 35.
5.15 Assignment of property values and their uncertainties		
5.15.1.a), b), c), d), f)	nil	These requirements are specific for reference materials and are not covered by ISO/IEC 17025 except for sub-clause e). Demonstration of the traceability of the property values must be in accordance with the requirements of ISO Guide 35.
5.15.1.e)	5.4.6.1, 5.4.6.2	
5.15.2	5.4.6.1, 5.4.6.2, 5.4.6.3	This requirement is specific for reference materials.

ISO Guide 34:2000	ISO/IEC 17025:2005	Remarks
5.16 Certificates and information for users	5.10	This requirement is specific for reference materials. The contents of the certificates must comply with the requirements of ISO Guide 31.

Annex 2: Cross-Reference between ISO/IEC 17025:2005 and ISO Guide 34:2000
(Informative)

ISO/IEC 17025:2005	ISO Guide 34:2000	Remarks
1 Scope	1 Scope	
2 Normative reference	2.Normative references	
3 Terms and definition	3 Terms and definitions	
4 Management requirements		
4.1 Organization		
4.1.1	4.2.1	
4.1.2	4.2.2	
4.1.3	4.2.2	
4.1.4	4.2.3.f)	
4.1.5.a)	4.2.3.a)	
4.1.5.b)	4.2.3.b)	
4.1.5.c)	4.2.3.c)	
4.1.5.d)	4.2.3.d)	
4.1.5.e)	4.2.3.e)	
4.1.5.f)	4.2.3.f)	
4.1.5.g)	Nil	
4.1.5.h)	4.2.3.g)	
4.1.5.i)	4.2.3.h)	
4.1.5.j)	4.2.3.i)	
4.1.5.k)	nil	4.1.5.k is a new requirement of ISO/IEC 17025:2005
4.1.6	nil	4.1.6 is a new requirement of ISO/IEC 17025:2005
4.2 Management system		
4.2.1	4.1.1, 4.1.3	
4.2.2	4.1.2	
4.2.3	nil	4.2.3 is a new requirement of ISO/IEC 17025:2005
4.2.4	nil	4.2.4 is a new requirement of ISO/IEC 17025:2005
4.2.5	nil	
4.2.6	4.1.3	
4.2.7	nil	4.2.7 is a new requirement of ISO/IEC 17025:2005
4.3 Document control		
4.3.1 General	4.3.1	
4.3.2 Document approval and issue		
4.3.2.1	4.3.2.1	
4.3.2.2	4.3.2.2	
4.3.2.3	nil	

ISO/IEC 17025:2005	ISO Guide 34:2000	Remarks
4.3.3 Document Changes		
4.3.3.1	4.3.3.1	
4.3.3.2	4.3.3.2	
4.3.3.3	4.3.3.3	
4.3.3.4	4.3.3.4	
4.4 Review of requests, tenders and contract		
4.4.1	4.4.1	
4.4.2	4.4.2	
4.4.3	4.4.3	
4.4.4	Nil	
4.4.5	Nil	
4.5 Subcontracting of tests and calibrations		
4.5.1	4.5.1, 4.5.2	
4.5.2	Nil	
4.5.3	Nil	
4.5.4	4.5.3	
4.6 Purchasing services and supply		
4.6.1	4.6.1	ISO Guide 34 does not require the procedures for purchase, reception and storage of reagents and laboratory consumables.
4.6.2	4.6.2, 4.6.3, 4.6.4	
4.6.3	Nil	
4.6.4	4.6.5	In addition to ISO/IEC 17025, ISO Guide 34 requires that the records include any quality assurance approval that is held by the suppliers and/or collaborators.
4.7 Service to the customer		
4.7.1	nil	
4.7.2	4.7	4.7.2 has been graded up as a new requirement from a note of clause 4.7 in ISO/IEC 17025:2005.
4.8 complaints	4.7	
4.9 Control of nonconforming testing and/or calibration network		
4.9.1	4.8.1	
4.9.1.a)	4.8.1.a), b), d)	
4.9.1.b)	4.8.1.c)	

ISO/IEC 17025:2005	ISO Guide 34:2000	Remarks
4.9.1.c)	4.8.1.e)	ISO Guide 34 does not specify the acceptability of the nonconforming work.
4.9.1.d)	4.8.1.f)	
4.9.1.e)	4.8.1.g)	
4.9.2	4.8.2	
4.10 Improvement	nil	4.10 is a new requirement of ISO/IEC 17025:2005
4.11 Corrective action		
4.11.1 General	4.9.1	
4.11.2 Cause analysis	4.9.2	
4.11.3 Selection and implementation of corrective actions	4.9.1, 4.9.3	
4.11.4 Monitoring of corrective actions	4.9.4	
4.11.5 Additional audits	nil	
4.12 Preventive action		
4.12.1	4.10.1	In addition to ISO/IEC 17025, ISO Guide 34 requires to review all operational procedures in a systematic way at regular intervals.
4.12.2	4.10.2	
4.13 Control of records		
4.13.1 General		
4.13.1.1	4.11.1.1	
4.13.1.2	4.11.1.2	
4.13.1.3	4.11.1.3	
4.13.1.4	4.11.1.4, 5.13.2.d	
4.13.2 Technical records		
4.13.2.1	4.11.1.1, 4.11.2	
4.13.2.2	nil	
4.13.2.3	nil	
4.14 Internal Audits		
4.14.1	4.12.1	
4.14.2	4.12.2	
4.14.3	4.12.3	
4.14.4	nil	
4.15 Management review		
4.15.1	4.9.5, 4.10.3, 4.13.1	
4.15.2	4.13.2	
5 Technical requirements		
5.1 General		
5.1.1	nil	

ISO/IEC 17025:2005	ISO Guide 34:2000	Remarks
5.1.2	nil	
5.2 Personnel		
5.2.1	5.1.1, 5.1.2	
5.2.2	5.1.2, 5.1.3	ISO Guide 34 does not cover the evaluation of the effectiveness of the training actions which was newly introduced into ISO/IEC 17025.
5.2.3	nil	
5.2.4	5.1.1	
5.2.5	5.1.1, 5.1.4	
5.3 Accommodation and environmental condition		
5.3.1	5.5.1	
5.3.2	5.5.1, 5.5.3	ISO Guide 34 does not cover the stoppage of the activities when the environmental conditions jeopardize the results of tests.
5.3.3	nil	
5.3.4	nil	
5.3.5	nil	
5.4 Test and calibration methods and method validation		
5.4.1 General	4.3.2.2.a), 5.10.1	ISO Guide 34 does not cover the deviation of the test methods.
5.4.2 Selection of method	nil	
5.4.3 Laboratory-developed method	nil	
5.4.4 Non standard methods	5.10.2	
5.4.5 Validation of methods		
5.4.5.1	nil	
5.4.5.2	5.10.2	
5.4.5.3	nil	
5.4.6 Estimation of uncertainty of measurement		
5.4.6.1	5.15.1.e), 5.15.2	
5.4.6.2	5.15.1.e), 5.15.2	
5.4.6.3	5.15.2	
5.4.7 Control data		
5.4.7.1	5.13.1	
5.4.7.2	5.13.2	
5.5 Equipment		
5.5.1	nil	

ISO/IEC 17025:2005	ISO Guide 34:2000	Remarks
5.5.2	5.11.1, 5.11.4	The requirement of ISO Guide 34 is only for measuring equipment.
5.5.3	nil	
5.5.4	nil	
5.5.5	nil	
5.5.6	nil	
5.5.7	5.11.2	
5.5.8	5.11.3	
5.5.9	nil	
5.5.10	5.11.1	
5.5.11	nil	
5.5.12	nil	
5.6 Measurement traceability		
5.6.1 General	5.11.4	
5.6.2 Specific requirements		
5.6.2.1 Calibration		
5.6.2.1.1	5.11.5, 5.12.1	
5.6.2.1.2	5.12.2	
5.6.2.2 Testing		
5.6.2.2.1	5.11.5, 5.12.1	
5.6.2.2.2	5.12.2	
5.6.3 Reference standards and reference material		
5.6.3.1 Reference standards	nil	
5.6.3.2 Reference materials	nil	
5.6.3.3 Intermediate checks	nil	
5.6.3.4	4.1.3.h)	
5.7 Sampling		
5.7.1	5.10.3	
5.7.2	nil	
5.7.3	nil	
5.8 Handling of test and calibrations		
5.8.1	4.1.3.h), i), 5.6.1	
5.8.2	4.1.3.i), 5.6.1, 5.6.5	
5.8.3	nil	
5.8.4	5.6.2	
5.9 Assuring the quality of test and calibration result		
5.9.1	nil	
5.9.2	nil	5.9.2 is a new requirement of ISO/IEC 17025:2005
5.10 Reporting the results		
5.10.1 General	5.16	

ISO/IEC 17025:2005	ISO Guide 34:2000	Remarks
5.10.2 Test report and calibration certificate	5.16	
5.10.3. Test Report	5.16	
5.10.4 Calibration certification	5.16	
5.10.5 Opinions and interpretations	nil	
5.10.6 Testing and calibration results obtained from subcontractors	nil	
5.10.7 Electronic transmission of results	nil	
5.10.8 Format of reports and certificates	nil	
5.10.9 Amendments to test reports and calibration certificates	nil	

ANNEX 3: Application of ISO/IEC 17025 to RMP Tasks
(Informative)

Stages/Tasks of (C)RM production	Relevant ISO/IEC 17025 Clauses
<u>Production planning</u>	
> Design project	Not applicable
> Select subcontractors (if needed)	4.4.3 (contract review); 4.5 (subcontracting)
Material preparation	
> Production planning	Not applicable
> Selection of materials	4.6 (purchasing)
> Production control	Not applicable
> Control of environment	5.3 (Accom. & environment.)
> Control of poor quality material	4.9 (Nonconforming product)
Homogeneity/Stability testing	
> Statistical Plan (ISO Guide 35)	5.3 (accom & envir.); 5.4 (test method & validation); 5.4.6 (MU); 5.5 (equipment); 5.6 (traceability); 5.7 (sampling)
> Calibration/testing homogeneity & stability (pre & post certification)	5.7 (sampling); 5.3 (accom. & environment); 5.4 (test method & validation); 5.5 (equipment)
<u>Characterization of Property Values</u>	
> Characterization of measurand	4.4 (contract review); 4.5 (subcontracting); 4.13 (records); 5.2 (personnel); 5.3 (accom. & environment); 5.4 (test method & validation); 5.5 (equipment); 5.6 (traceability); 5.7 (sampling); 5.8 (handling items); 5.9 (QC); part of 5.10 (reports)
> Method selection	5.4 (test method & validation)
> Method validation	5.4 (test method & validation)
> Quality assurance	5.9 (QC)
> Traceability of measurement results	5.5 (equipment);

Stages/Tasks of (C)RM production	Relevant ISO/IEC 17025 Clauses
	5.6 (traceability)
> Uncertainty of measurement	5.4.6 (MU)
<i>Assignment of and Decision on Property Values</i>	
> Data evaluation	5.4.6 (MU); 5.4.7 (data control)
> Identification of bias	5.9.2 (QC)
> Statistical procedures	5.4.1 (test method & validation)
> Traceability of property values to SI/stated reference	5.6 (traceability)
> Uncertainty of property value	5.4.6 (MU)
<i>Authorization of property values and issue of certificate</i>	Not applicable
<i>Handling and storage (including post certification testing)</i>	
> Packaging & labeling	5.8 (handling items)
> Monitoring integrity of RM during storage	5.8 (handling items)
> Monitoring storage temperature & environment	5.3 (accom. & environment.) (4.13: records)
<i>Distribution & Post Distribution Services</i>	Not applicable

Note: The above are just examples of some of the ISO/IEC17025 requirements that are considered as applicable, in most of the cases, to the RMP tasks.