



**ACCLASS Guidance on ISO Guide 34
Reference Material Producer (RMP)
Accreditation**

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Purpose

The purpose of this guidance document is to further explain aspects of the ACLASS ISO Guide 34 Reference Material Producer (RMP) accreditation program. This document is intended to give ACLASS customers, assessors and experts the necessary understanding of reference material producer competency and management issues in order to achieve, assess and/or maintain accreditation to ISO Guide 34.

This guidance document applies to all applicant and accredited ACLASS customers.

Definitions

Reference material producer (RMP): Technically competent body (organization or firm, public or private) that is fully responsible for project planning and management, assignment of and decision on property values, authorization of property values and issue of the certificate or other statements for the reference materials it produces.

Collaborator: Technically competent body (organization or firm, public or private) that undertakes aspects of the processing, handling, homogeneity and stability assessment, characterization, storage or distribution of the reference material on behalf of the reference material producer, either on a contractual or voluntary basis.

NOTE 1: Key tasks/aspects of the reference material production process which cannot be performed by external parties are project planning, assignment and decision on property values and relevant uncertainties, authorization of property values and issuing of certificates or other statements for non certified reference materials.

NOTE 2: The term 'collaborator' has similarities to the term 'sub-contractor' as used in ISO/IEC 17025.

Production: in this Guide the meaning of production includes all necessary activities and tasks leading to a reference material (certified or non-certified) supplied to customers and includes production planning, production control, material handling and storage, material processing, assessment of homogeneity and stability, characterization, assignment of property values and their uncertainties, authorization and issue of certificates or other statements and post-distribution service of the reference materials.

NOTE: Production is not restricted to the manufacture and preparation of the candidate materials used for the production of reference materials.

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: RM is a generic term.

NOTE 2: Properties can be quantitative or qualitative (e.g. identity of substances or species).

NOTE 3: Uses can include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.

NOTE 4: An RM can only be used for a single purpose in a given measurement.

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

NOTE 1: The concept of value includes qualitative attributes such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities.

NOTE 2: Metrologically valid procedures for the production and certification of reference materials are given in, among others, ISO Guide 34 and Guide 35.

NOTE 3: ISO Guide 31 gives guidance on the contents of certificates.

Commutability (according to ISO 17511): Closeness of agreement between the mathematical relationship of the measurement result by two measurement procedures for a stated quantity in a given material, and the mathematical relationship obtained for the quantity in routine samples.

NOTE: (by the editor) For reference materials the emphasis of commutability lies in comparing the behaviour of certified reference materials and routine samples in the measurement or testing process.

Proficiency Testing: The determination of a laboratory's calibration/testing performance, usually by use of inter-laboratory comparisons. A laboratory's participation in proficiency testing enables the laboratory to assess and demonstrate the reliability of the resultant measurement data by comparison with results from other participating laboratories.

ACLASS RMP Requirements and Assessment Guidelines

ACLASS requirements for RMP accreditation are outlined in Document 5 for Reference Material Producers. These requirements include showing evidence of successful participation in relevant proficiency testing prior to granting of initial accreditation. If proficiency testing is not available for a particular measurement discipline or parameter through existing proficiency testing programs, then alternatives may be considered including internal performance-based data demonstrating laboratory competence and measurement performance, if possible in comparison with another laboratory entity. These alternatives may be substituted for the traditional proficiency testing programs, which could allow a laboratory to achieve initial accreditation and still meet the ACLASS requirement.

Laboratories accredited by ACLASS are highly encouraged to select proficiency testing providers that can demonstrate their programs are accredited to ISO/IEC 17025 and comply with

the requirements of ISO Guide 43-1 and the ACLASS proficiency testing guidance document.¹ Where appropriate accredited proficiency testing providers are not available, laboratories should use programs that operate in accordance with ISO Guide 43-1 as fully as possible.

The basic auditing document for RMP accreditation is ISO Guide 34 which has many similarities to ISO/IEC 17025. Guide 34, however, encompasses much more than the testing laboratory operations which is the focus of any ISO/IEC 17025 accreditation. Guide 34 also references and presumes that RMP organizations maintain compliance to related ISO guides, Guide 30 (definitions), Guide 31 (labels and certificates), and Guide 35 (Statistics and uncertainty estimations).

RMP accreditation is also most often an extension of technical and management accreditation to ISO/IEC 17025. Should the RMP organization not have a laboratory related to the RMP reference material testing, however, the RMP organization may seek only accreditation to ISO Guide 34.

Why the Need for PT/ILC in RMP Accreditation?

ACLASS, in following ISO/IEC 17025 and ILAC guidance² for proficiency testing and inter-laboratory comparisons, believes the use of proficiency testing/inter-laboratory comparisons is to assure that every accredited laboratory is:

- Receiving a regular comparison with other laboratories relative to their technical proficiencies and accuracies
- Striving to adhere as closely as possible and practical to ISO Guide 43 in the conduct of this proficiency testing/inter-laboratory comparison
- When feasible, participating in commercially-provided proficiency testing/inter-laboratory comparison schemes; or designing their own to meet the intent of ISO Guide 43-1 and ISO/IEC 17025
- When not feasible, unreasonably cumbersome or expensive, designing their own proficiency testing/inter-laboratory comparison program and ensure the program complies, in good faith, to the ACLASS requirements
- Showing evidence of satisfactory proficiency testing/inter-laboratory participation prior to initial accreditation. If no proficiency testing/inter-laboratory participation plan or initial activity is in place at the time of accreditation, a major non-conformance will be written. If the plan is in place, but no report is yet in hand to verify satisfactory participation, a minor non-conformance will be written. While accreditation can be

¹ ISO Guide 43-1 is expected to be superseded by ISO/IEC 17043 in 2010.

² Suggested ILAC Guidance includes: ILAC G13:2000 Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes and ILAC G22:2004 Use of Proficiency Testing as a Tool for Accreditation in Testing

secured as a result of the minor non-conformance, it may be withdrawn if no verification is in place within 6 months of accreditation.

- Obtaining regular feedback, which includes analyses of the quality control data, from their proficiency testing/inter-laboratory comparison provider(s) regarding relative competence and accuracy so as to initiate warranted corrective actions in their quality system to correct any problems and to prevent incorrect results from being reported. The use of normalized results via E_n or z-values allows easy and internationally recognized feedback, and is therefore generally preferred.

RMP Technical Areas

The potential accredited areas encompassed in the RMP arena may entail any of a lengthy list of materials used for critical and measurable properties in the biological, chemical, clinical, pharmacological, food, physical, mechanical, engineering, environmental, and forensic sciences. Much of the value for RMP accreditation, however, relates to international confidence in the RMPs themselves. This leads to international trade assurances, and assurances that international guidelines are followed in the production, labeling, assignment of property values to the materials, including stability and homogeneity determinations. ACLASS has listed those potential areas in the attached RMP Category/Types form appended to this guidance document.

Potential RMP accredited organizations are encouraged to define and declare all relevant areas from this ACLASS listing in their application for RMP accreditation. This full listing will be used to determine the time projected for sufficient witnessing and verification during the initial and future accreditation visits. It should be noted that not only general categories and types of RMPs, but also matrix definitions, range designations and other details will also be part of the eventual accredited scope for an RMP.

Similarities/Overlaps to ISO/IEC 17025 Accreditation

The latest published revision to ISO Guide 34 (2008) has an Appendix B which demonstrates a cross reference table between ISO/IEC 17025 and ISO Guide 34. It distinguishes those elements of each that are unique and which elements are essentially identical for verification / auditing purposes.

One of the key overlaps between ISO/IEC 17025 and ISO guide 34 accreditation is the requirement for participation in relevant PT/ILC schemes. ACLASS requires all accredited Guide 34 customers to participate annually (unless they do not have a laboratory that performs key testing related to the RMP accreditation itself) in PT programs essentially similar to those required for ISO/IEC 17025 accreditation. Guide 34 customers are instructed to review the ACLASS Guidance Document for Proficiency Testing for more information in this regard. Laboratories must promptly review and analyze proficiency test/inter-laboratory comparison results, and if the results are found to be outside pre-defined criteria (i.e. unsatisfactory results), corrective actions shall be promptly taken and submitted to ACLASS

The ACLASS suggested PT/ILC summary form (Form 15) is normally sufficient to satisfy this requirement. This summary is generally part of the report from each visit but is also retained separately in a client proficiency testing/inter-laboratory comparison file. Submission of the entire proficiency testing/inter-laboratory comparison report is also acceptable in lieu of the summary report form.

Also appended to this document is a full matrix from the related ILAC RMP guidance document that highlights differences between ISO Guide 34 and ISO/IEC 17025 requirements.

RMP Appendix A -- Reference Material Producer Categories and RM Types

Category 1 -- Chemical	
<p>A – Metals</p> <ul style="list-style-type: none"> • Ferrous • Non-ferrous • Alloys • Rare earths • Solutions • Other, specify ____ <p>B – Other Inorganics</p> <ul style="list-style-type: none"> • Ores / minerals / pure or mixed compounds • Clays and cements • Ceramics and glass • Agricultural and fertilizers • Coal and coke • Isotopes <p>C – Organics</p> <ul style="list-style-type: none"> • Pure compounds • Drugs and pharmaceuticals • Pollutants • Herbicides and pesticides • Agricultural chemicals / fertilizers • Foodstuffs • Plastics • Rubber • Petroleum products • Oils and fats <p>D – Environmental materials</p> <ul style="list-style-type: none"> • Soils and sludges • Ashes / flyash • Waters • Plant / agricultural material • Marine material • BOD and inocula material • Other, specify ____ 	<p>E -- Health and Hygiene</p> <ul style="list-style-type: none"> • Clinical laboratory materials • Solvents • Biological samples (urine, hair) • Filter samples • Paint and construction materials • Other, specify ____ <p>F – Engine Wear</p> <ul style="list-style-type: none"> • Metallo-organic • Metals in oil <p>G – Gases</p> <ul style="list-style-type: none"> • Pure gases or mixtures • Gases in metals • VOCs • Others, specify ____ <p>H – Forensic materials</p> <ul style="list-style-type: none"> • Ethanol, solvents, accelerants • Drugs and metabolites • Glass • Paint • Explosives • Residues • Biological samples • Fabric and fibers, incl. asbestos • Noxious and toxic materials <p>I – Solutions and other liquids</p> <ul style="list-style-type: none"> • pH and conductivity • Ion selective standards • Buffers and other solutions • Other, specify ____

<p>Category 2 – Biological and Clinical</p>	<p>Category 4 -- Engineering</p>
<p>A – General medicine</p> <p>B – Clinical Chemistry</p> <p>C – Tissue Pathology</p> <p>D – Hematology and Cytology</p> <p>E – Immunology and immuno-hematology</p> <p>F – Bacteriology / Mycology / Virology</p> <p>G – Pharmaceuticals and pharmacology (antibiotics, drugs, vaccines)</p> <p>H – Parasitology</p> <p>I – DNA / RNA, including Nucleic Acid probes</p> <p>J – Other, specify ____</p>	<p>A – Surface finish (roughness, corrosion, wear, thickness)</p> <p>B – Particle size and surface area</p> <p>C – Non-destructive</p> <p>D – Hardness</p> <p>E – Charpy impact</p> <p>F – Tensile / elasticity / creep</p> <p>G – Fire safety</p>
<p>Category 3 – Physical</p>	<p>Category 5 -- Other</p>
<p>A – Optical properties (opt. rotation, absorbance, reflectance, color)</p> <p>B – Electrical and magnetic properties (dielectric strength, resistivity, magnetism)</p> <p>C – Frequency standards</p> <p>D – Radioactivity</p> <p>E – Thermodynamic properties (calorimetry, conductivity, pressure, boiling pt.)</p> <p>F – Physicochemical properties (density, viscosity, surface tension, mol. wt.)</p> <p>G – Others, specify ____</p>	<p>A -- Specify anything not covered above</p>

RMP Appendix B (from ILAC RMP Guidance document) -- GAP
ANALYSIS BETWEEN ISO GUIDE 34 AND ISO/IEC 17025

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)	

ISO Guide 34:2000	ISO/IEC 17025:2005	Remarks
4.2.3.g)	4.1.5.h)	
4.2.3.h)	4.1.5.i)	
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

ISO Guide 34:2000	ISO/IEC 17025:2005	Remarks
		the suppliers and/or collaborators.
4.7 Client feedback	4,7.2, 4.8	
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	

ISO Guide 34:2000	ISO/IEC 17025:2005	Remarks
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	
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	
<i>5 Technical and production requirements</i>		
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

ISO Guide 34:2000	ISO/IEC 17025:2005	Remarks
		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	
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

ISO Guide 34:2000	ISO/IEC 17025:2005	Remarks
		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.
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	

ISO Guide 34:2000	ISO/IEC 17025:2005	Remarks
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	
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

ISO Guide 34:2000	ISO/IEC 17025:2005	Remarks
5.15.1.e)	5.4.6.1, 5.4.6.2	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.
5.15.2	5.4.6.1, 5.4.6.2, 5.4.6.3	This requirement is specific for reference materials.
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.

Revision History

Date	Description
November 15, 2008	Initial Draft – B. Hirt
May 1, 2009	Second round of updates – B. Hirt
August 5, 2009	Final review – K. Greenaway