

Policy, Requirements and Conditions for Reference Material Producer Accreditation Bureau of Laboratory Quality Standards, Department of Medical Sciences

A. Tanunkat, W. Piyasiranond, and C. Sinthusarn

Bureau of Laboratory Quality Standards, Department of Medical Sciences, Bangkok, Thailand

Abstract

Reference materials are material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus. The assessment of a measurement method, or for assigning values to materials. If a reference material accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence are called certified reference materials. The producers of reference material and certified reference material shall demonstrate their competence by formal compliance with a set of internationally recognized criteria. They shall accredit by the accreditation body who's signed MRA with APLAC.

The Bureau of Laboratory Quality Standards (BLQS) which is an accreditation body was approved to be a full member and signatory to APLAC MRA in the scope of testing laboratory accreditation for ISO/IEC 17025 and ISO 15189 on November 14, 2002 and on April 18, 2007, respectively. Set an accreditation program for Reference Material Producers since 2006 for training the staff and set criteria for accredited. In October 2013, BLQS expanded its Asia Pacific Laboratory Accreditation Cooperation Mutual Recognition Arrangement (APLAC MRA) Scope to include the Reference Material Producer Accreditation Program. This arrangement calls for the signatory Accreditation Bodies to operate to ISO/IEC 17011 and assess reference material producers to ISO Guide 34 in combination with ISO/IEC 17025. This program is designed for producers of certified reference materials and reference materials who wish to demonstrate their competence by formal compliance with a set of internationally recognized criteria. The program will also provide users of reference material, such as testing and calibration laboratories, with increased confidence that the reference materials being relied upon are being produced in accordance with specified technical and management system requirements and are of appropriate quality.

Keyword: Reference material, Accreditation, ISO guide 34

INTRODUCTION

Bureau of Laboratory Quality Standards (BLQS) shall provide a high quality accreditation and technical services to accredit reference material producers (RMP) comply with ISO Guides 34¹ in combination with ISO Guides 31² and 35³ plus ISO/IEC 17025⁴. Our processes for such accreditation

offer applicant bodies the opportunity to assure their customers of their compliance with the relevant international standards. Reference material producers (RMP) accreditation process of BLQS shall be managed by the director of BLQS who has been endorsed by the government authoritative to operate all activities independently. The accreditation

*Corresponding author: Bureau of Laboratory Quality Standards, Department of Medical Sciences

shall be impartial among all organization, both with internal and external agencies of DMSc.

BLQS shall ensure the accreditation system of RMP to comply with ISO 17011⁵, *Conformity assessment-General requirements for the accreditation bodies accrediting conformity assessment bodies*, APLAC and ILAC MRA requirement in order to have international recognition of the accreditation scheme. BLQS also uses the current version of the APLAC TC008⁶ *Requirement for and guidance on the Accreditation of a Reference Material Producer and the resulting Scope of Accreditation* and APLAC TC 012⁷. *Guidelines for the acceptability of Chemical Reference Material and Commercial Chemical for Calibration of Equipment used in Chemical Testing*.

TYPES OF RMP

Reference Material Producer contains many stages of activities (tasks of RMP), some of this can be subcontracted. The types of RMP classified by number of task the RMP performed. Table 1 demonstrates the types of RMP and the responsible tasks for each type of RMP as well as the relevant standard (ISO) applied to each stage.

According to APLAC TC 008 (APLC Requirements for and Guidance on the Accreditation of a Reference Material Producer and the Resulting Scope of Accreditation)⁹, the principles apply to the assessment and accreditation of RMPs are as follows:

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 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 RM supplied to customers, and includes at least those given in the table (Table 1). In other words, production is not restricted to just the manufacture and preparation of the

candidate material. Where an organization only provides services such as provision of reference values to a candidate RM, it cannot be considered as a RMP.

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 organizational structure of the RMP facility.

An RMP may choose or require the use of subcontractors to perform various tasks leading to the production of its RMs, and its role may change in relation to the 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 products (RMPs), an accredited RMP is an organization that assigns the property values and determines the associated uncertainties (ISO Guide 34 clause 5.15) and issues the certificate (ISO Guide 34, 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.

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

The following table (Table 1) 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.

Table 1. Stages / Tasks of (C) RM production relevant to ISO Guide 34 in combination with ISO/IEC 17025 and responsible organizations.

| Stages / Tasks of RM production | Relevant ISO Documents | Responsible organizations | | | | | | | |
|--|---------------------------------|---------------------------|--------|--------|--------|--------|--------|--------|--------|
| | | Type 1 | Type 2 | Type 3 | Type 4 | Type 5 | Type 6 | Type 7 | Type 8 |
| Production | ISO Guide 34 + | R | R | R | R | R | R | R | R |
| Planning | ISO/IEC 17025 | | | | | | | | |
| # Material | ISO Guide 34 + | R | S | S | S | S | R | S | R |
| Preparation** | ISO/IEC 17025 | | | | | | | | |
| # 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* |
| Assignment of and Decision on Property Values | ISO Guide 34 + ISO/IEC 17025 | R | R | R | R | R | R | R | R |
| Authorization of Property values and Issue of certificate | 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 = Tasks 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.

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

a) A single organization 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 organization 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 organization 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 organization 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 organization 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).

Scopes

Area of Reference Material Producers may cover the list of materials used for critical and measurable properties in the chemical, biological, clinical, pharmacological, food and forensic sciences.

These requirements shall assure that the relevant international standards are followed in the production, labeling, assignment of property values to the materials, including stability and homogeneity which are then factored in the Reference Material Procedures uncertainty reported.

The international standard used for accreditation and the combination of international standards are as follows :

ISO Guide 34⁷: General requirements for the competence of reference material procedures.

In-combination with:

ISO/IEC 17025⁴: General requirements for the competence of testing and calibration Laboratories.

ISO Guide 30^{8,9}: Terms and Definitions Used in Connection with Reference Materials.

ISO Guide 31²: Contents of Certificates of Reference Materials

ISO Guide 35³: Certification of Reference Materials - General and Statistical Principles.

The specific types of CRMs and RMs that the RMP is competent to produce is mentioned in the Table 1: Stages / Tasks of RM production relevant to ISO Guide 34 in combination with ISO/IEC 17025 and responsible organizations. The range of property values for the (C) RMs with the associated uncertainties, where relevant, for which the RMP is accredited.

Categories and sub-categories of reference materials are given in **Appendix 1**¹⁰ (as mentioned in Appendix B of ILAC G 12) which is a good guidance to describe the specific types of RMs for which a RMP is accredited.

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.

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.

As an RMP can do various tasks (refer to Table 1), accreditation shall be granted to it for those activities that has been assessed and found to meet the relevant requirements. The scope of accreditation, of 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.

DEFINITIONS

RMP Accreditation:

Procedure by which the BLQS, DMSc gives formal recognition that the RMP has the management comply with the related International Standards and BLQS, DMSc quality requirements and RMP is competence to carry out specific types of CRMs or RMs as listed in the scope of accreditation.

Technical Sub-Committee:

Technical sub-committee for RMP is appointed by the Director of Bureau of Laboratory Standards. Technical sub-committee consists of technical experts in each discipline covering all scopes categories of RMP accreditation.

Laboratory Accreditation Committee:

Laboratory Accreditation Committee for Public Health Laboratories & RMP and Laboratory Accreditation Committee for Medical Laboratory are appointed by the Director of BLQS. The committee consists of necessary stakeholders who are representatives from other organizations such as NAC, FDA of Thailand, Department of Science Services (DSS), Associations etc.

Certified Reference Material :

Reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

Reference Material:

Material or substances one or more

if whose property values are sufficiently homogenous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. (Noted: A reference material may be in the form of a pure mixed gas, liquid, or solid)

Traceability:

Property of the result of a measurement or the value of a standard whereby it can be related, with a stated uncertainty, to stated reference, usually national or international standards, through an unbroken chain of comparison.

Proficiency Testing (PT):

Laboratory testing performance is determined by an accredited PT provider, using inter-laboratory comparison

QUALIFICATION OF THE RMP APPLICANTS

The RMP must be legal identifiable. All practices shall comply to Thailand laws and regulations. For cross frontier accreditation, the laws and regulations of certain country must be complying with. The laboratory may comprise permanent laboratory facilities, with or without sites away from its permanent or in associated temporary or mobile facilities.

GENERAL REQUIREMENTS

The top management of the RMP or the authorized representative shall sign the application form.

Each applicant must nominate a senior staff member who will represent one in all nominations in all dealings with BLQS. This person shall take responsibility for communication between top management and BLQS,

All details of the quality management system and the implementation document, which are fulfill the requirements of the BLQS, shall be submitted. BLQS will terminate the application if the documents are not completed within 180 days, after the date of submitting the application.

The RMP shall comply with the accreditation procedure and shall pay fee as scheduled and conditioned by BLQS.

The RMP shall cooperate with the assessors in the following;

Permit the access to the premises.
Prepare for test sample and hand on analysis for witness as requested by the assessor.

Assist and allow the use of the office stationary and the communication apparatus as necessary.

The administrators and the analysts have to work independently and have no conflict of interest that may adversely affect the quality of their works.

In case of any amendment or any changes of the Policy, Requirements and Conditions BLQS shall inform the accredited laboratory, both via official letter and on BLQS' web' pages. The accredited laboratory shall commit to follow such changes.

BLQS may reduce the scope or terminate the accreditation when if the RMP does not practice as described in 4.7., or there is any indicating to demonstrate that the scope of accreditation is not complied with the requirements of the standards under the consideration of the assessors, the laboratory accreditation committees or the technical sub committees of laboratory accreditation.

In case that the applicant RMP is in the process of accreditation or has already been accredited from the BLQS and the RMP intends to withdraw the accreditation, the RMP shall inform the BLQS, officially, in written do, the director of BLQS. The RMP cannot refund fee for accreditation.

QUALITY REQUIREMENTS

The RMP shall implement the requirements of ISO Guide 34 in combination with ISO/IEC 17025 and other relevant international standards including the policy and requirements of BLQS, DMSc.

The testing laboratory shall participate in proficiency testing program or inter-laboratory comparison as required by the Policy, Requirements and Conditions of BLQS.

THE ACCREDITATION PROCESS

The RMP shall submit the application No. 11 and Application form No. 12 to the BLQS. After the acceptance of the application, the BLQS will proceed as follow :

Examines the completeness of the documents, the result of proficiency testing or interlaboratory comparison, and then inform the applicant to pay the fee as indicated by BLQS.

Appoints the assessors after all of documents are ready for accreditation.

Pre-assesses, if it is required by the applicant, the laboratory is notified of the date, time, and the assessors' name. The assessors will assess the QA manual, related documents at the laboratory premise as pre-assessment. BLQS will inform the name of assessors and the date of pre-assessment before conduct the assessment.

Inform the pre-assessment results to the laboratory by sending the official report of pre-assessment.

Informs the name of the assessors and appoint the date of the on-site assessment after the applicant laboratory submits the corrective actions form of the pre-assessment. In case that applicant laboratory does not request for pre-assessment the processes in the item 7.2.3 and 7.2.4 are omitted. BLQS will inform the name of the assessor and appoint the date of the on-site assessment, together with the accreditation fee and then the assessment will be carried out.

The RMP shall correct all nonconformities in the timescale of the requirements for accreditation process of the BLQS. The duration for corrective action begins on the date of closing meeting for the assessment. The table of findings, corrective actions and supportive evidences, both in the electronic and the current copy, are to be sent to BLQS. The timescale of corrective action for the nonconformities from the various assessments are mentioned as following :

For Re-assessment, the RMP shall submit the corrective action within 30 days. In case that the RMP cannot complete the corrective action within 30 days, the RMP may extend the duration of corrective action

for another 30 days, in written, to the director the BLQS, with the reason and the approximate date for completion of corrective action. After that date, BLQS shall immediately conduct the on-site assessment.

For on-site assessment of new accreditation/extension corrective action for the nonconformities shall be carried out within 90 days. In case that the RMP cannot complete the corrective action, within 90 days, the RMP can extend the duration of corrective action, in written, to the Director of BLQS with the reason and the approximate date for completion of corrective action. However, the duration of corrective action and closed out shall be done within 180 days. If the RMP carried out the corrective action longer than 180 days, the BLQS shall conduct the follow up assessment for ensuring that the RMP still maintain the quality management system complying with the international standard and the requirements of the BLQS. For follow up or extra ordinary follow up, the RMP shall carry out the corrective action within 15 days. If the RMP cannot complete the corrective action within the time frame given, BLQS shall reduce the scope of accreditation. All expenses from extra ordinary follow up are the responsibility of the RMP.

For surveillance and re-assessment of the accreditation, the RMP shall carry out the corrective action of nonconformity within 30 days. In case that the RMP cannot complete the corrective action within 30 days, the RMP can extend the duration of corrective action for another 30 days, in written, to the Director of BLQS with the reason and the approximate date for completion of corrective action. If the RMP cannot complete and closed out the corrective action within the timeframe given, BLQS shall suspend the accreditation of that RMP and shall withdraw the accreditation if the RMP cannot renewal its accreditation within the timeframe given from suspension.

For combination between surveillance and extended scope of accreditation, the RMP, shall carry out the corrective action of nonconformities from the assessment within 30 days. In case that the RMP cannot

complete the corrective action within 30 days, the RMP can extend the duration of corrective action for another 30 days, in written, to the Director of BLQS with the reason and the approximate date for completion of corrective action. For extension scope of accreditation, the RMP shall carry out corrective action of the nonconformities from management requirements within 30 days and shall carry out corrective action of the nonconformities from technical requirements within 90 days. In case that the RMP cannot complete the corrective action within 90 days, the laboratory can extend the duration of corrective action as mentioned above in the item 6.2.6.2

BLQS will issue the certificate of accreditation after the RMP Accreditation Committee grants the approval.

The accreditation certificate is valid for 2 years from the issue date. It can be extended for every 2 years if the request for the extension is received by BLQS 120 days prior to the expiry date. The certificate shall be issued in Thai and English languages.

If the accreditation certificate is lost, it can be replaced if the laboratory can submit the evidence within 15 days of the incident. Payment shall be following as fee schedule determined by BLQS.

PRACTICES FOR THE ACCREDITED RMP :

Maintains quality management system compliance to the accreditation certificate of the international standard of ISO Guides 34 in combination with and BLQS's requirements at all time of accreditation.

Optionally uses BLQS accreditation symbol and/or accreditation statements. In both cases, the accredited RMP shall inform BLQS the intention to use the BLQS accreditation symbol and/or accreditation statements.

Correctly uses the BLQS accreditation logos/or symbols and/or statements. BLQS will take necessary actions against the accredited RMP or individuals who misused any of the BLQS accreditation logos/or symbols and/or statements in the

way of incorrect references or misleading or misrepresentation, for example using BLQS accreditation symbol for unaccredited test and/or an authorized approved signatory. In these cases, the accredited RMP shall be suspended of accreditation for 90 days and might be sentenced by law.

Shall immediately stop using or shall not claim BLQS accreditation symbol or reference to its accredited status for the activities which are suspended withdrew or reduced the scope of accreditation. Such misusages might result in legal responsibility. The accredited RMP shall inform its customer for its accredited status.

Shall not do anything which may mislead that the granted accreditation is BLQS' certification for the product quality.

Shall inform BLQS, within 15 days, if there is any change from the application forms.

Legal status or business status and organization chart.

Top management who make a decision for the organization management

Policy and work procedures in the quality documents.

Personnel, equipments, environment that have an effect directly to the test results.

Approved signatories for the accredited tests.

The claim or the use of BLQS accreditation symbol.

Others changes that may affecting the competency of the laboratory

Collection and storage of all quality documents for at least 3 years, therefore, the documents can be traceable.

SURVEILLANCE

Surveillance assessment for the accredited RMPs with their RMPs accreditation certificates of 2 years shall be done as follows :

On-site surveillance assessment shall be done if there is any evidence indicates that the accredited laboratories cannot maintain their quality management system or it is the consensus decision from the technical sub-committees, or from RMP accreditation committees.

The accredited RMP shall submit the quality documents for surveillance assessment to the BLQS in advance, at least 60 days.

REASSESSMENT

Reassessment shall be taken place at intervals not exceeding than 2 years. Accredited RMP shall submit the quality documents to BLQS in advance, at least 120 days before the expiry date of accreditation certificate. BLQS shall carry out on-site reassessment in the timeframe of reassessment plan.

Accredited RMP shall submit the quality documents for reassessment to BLQS in advance and shall pay for accreditation fee as indicated.

EXTENSION SCOPE OF ACCREDITATION (EXTENDING ACCREDITATION)

Accredited RMP can request for an extension the scope of an accreditation to BLQS under the timeframe as follows:

Shall apply for extension scope of accreditation at the same time of reassessment and pay for accreditation fee as indicated.

In case that accredited RMP needs to apply for extension scope of accreditation before the time of reassessment, the accredited RMP shall inform the urgent necessary for extension to BLQS and get the approval for extension from the Director of BLQS. Such special application will cost 2 times more from the normal rate.

Shall request for extension scope of accreditation in advance at least 30 days and officially submit all of application forms together with the related quality documents to BLQS. BLQS shall carry out the on-site extension in the same manners as in the initial assessment.

WITHDRAWAL / SUSPENSION OF THE ACCREDITATION

Withdrawal of the accreditation

The committee will withdraw the accreditation under the following circumstances.

The RMP has become bankruptcy by court order.

Any practice that violate or do not comply with the Act for “Thai National Standards” B.E. 2551 and the BLQS’s requirements.

The RMP terminates its business.

The RMP shall inform the termination by officially document to BLQS.

Suspension of the accreditation

The Director of BLQS, DMSc will declare a temporary suspension of the accreditation if the RMP does not follow the Policy, Requirements and Conditions of the BLQS and cannot correct the non-conformities within a given time frame, if the accredited laboratory cannot correct and close out the nonconformities within a given timeframe again, BLQS will withdraw or reduce the scope of the accreditation, accordingly.

APPEAL

The appeal for any decisions shall be submitted in written to the Secretary-General of Thai Industrial Standards Institute (TISI), Ministry of Industry within 15 days upon receipt of the withdrawal letter.

The decision of Ad-hoc Appeal Committee for Laboratory Accreditation’s decision is a final.

During the appeal, the accreditation is still valid.

USE OF ACCREDITATION SYMBOL

The accredited RMP shall demonstrate or show the accreditation symbol as defined in “the Policy, Requirements and Conditions for using of Accreditation Symbol N 07 15 009”.

RMP shall inform the BLQS of the detail of the symbol exhibition.

The symbol shall not be abused, misused, or misleader in the accreditation. Misuse of those symbols to their accreditation status or in any form of the BLQS, Policy may be also legal penalties. The accredited

RMP shall be suspended of accreditation for 90 days if it uses the accreditation symbol and/or accreditation statements out of its scope of accreditation, may be punished according to the law.

MISCELLANEOUS

BLQS shall inform in written to the RMP of any changes in the requirements, which shall be corrected and adjusted within the time frame.

The BLQS shall not take any responsibility if the RMP does not conform to the policy, requirements and conditions of the BLQS.

The accredited or withdrawn RMP names, tests, methods and accreditation number will be announced in the website: www.dmsc.moph.go.th, or <http://blqs.dmsc.moph.go.th>

Interested party shall submit the application to BLQS, within the Ministry of Public Health, Nonthaburi.

APPENDIX 1

CATEGORIES OF REFERENCE MATERIAL (ILAC G 12: 2000)

Category A: Chemical composition

Reference materials, being either pure chemical compounds or representative sample matrices, either natural or with added analytes (e.g. animal fats spiked with pesticides for residues analysis), characterized for one or more chemical or physicochemical property values.

Category B: Biological and clinical properties

Materials similar to Category A, but characterized for one or more biochemical or clinical property values.

Category C: Physical properties

Materials characterised for one or more physical property values, e.g. melting point, viscosity, density.

Category D: Engineering properties

Materials characterised for one or more engineering property values (e.g. hardness, tensile strength, surface characteristics, etc).

Category E: Miscellaneous

These principal categories are subdivided into subcategories as indicated in the following draft list. It should be noted that these sub-categories are indicative only. Other sub-categories can be added at any time to address the needs of applicants seeking recognition of competence in producing types of reference materials not currently listed.

CATEGORY A: CHEMICAL COMPOSITION

*INORGANIC REFERENCE MATERIALS***Pure chemicals**

Stoichiometry standards
 Primary standards
 Working standards
 Secondary standards
 Chromatography standards
 Pharmaceutical materials
 Cosmetic materials

*ORGANIC REFERENCE MATERIALS***Pure organic compounds**

Compounds for elemental analysis
 Compounds for molecular weight
 Chromatography standards
 Illicit drugs and their metabolites -
 (See also A8 Forensic Reference Materials)
 Illicit drugs
 delta-9-THC and other cannabinoids
 Amphetamine
 Methylamphetamine
 3, 4-methylenedioxyamphetamine
 3, 4-methylenedioxy-methylamphetamine

3, 4-methylenedioxy-ethylamphetamine
 Diacetylmorphine
 Morphine
 Cocaine
 Lysergic acid diethylamide and isomers
 Therapeutic drugs
 Veterinary drugs
 Steroids
 Pesticides, herbicides, acaricides, etc
 Metabolites of any of the above
 Priority pollutants
 PCBs, PAHs, etc
 Fine chemicals
 Pharmaceutical materials
 Cosmetic materials
 Isotopically labeled compounds

Foodstuffs

Proximate analysis
 Nutritional properties
 Vitamins
 Other food additives
 Antioxidants
 Emulsifiers
 Trace elements
 Trace organics
 Pesticide residues
 Other organic contaminants

*HEALTH AND INDUSTRIAL HYGIENE***Clinical laboratory materials**

Ethanol solutions

*FORENSIC REFERENCE MATERIALS***Ethanol reference standards**

Ethanol
 Ethanol, aqueous solutions containing
 0.050, 0.150, 0.250 g/100mL

*ION ACTIVITY***pH standards**

Ion selective electrode calibrants

Conductivity standards

Buffer systems

CATEGORY B: BIOLOGICAL AND CLINICAL PROPERTIES

General Medicine

Human serum materials (powder and solution forms)

Clinical Chemistry

Proteins

Apo lipoproteins

Enzymes

Hormones

Trace elements

Lead and cadmium

CATEGORY E: MISCELLANEOUS PROPERTIES

(Sub-categories to be developed as required)

ACKNOWLEDGEMENT

Bureau of Laboratory Quality Standards would like to thank very especially Dr. Panadda Silva who is advising and reviewing for this article.

REFERENCES

1. ISO Guide 34:2009. General requirements for the competence of reference material procedures.
2. ISO Guide 31: 2000. Reference materials - Contents of certificates and labels.
3. ISO Guide 35: 2006. Reference Materials - General and statistical principles for certification.
4. ISO/IEC 17025: 2005. General requirements for the competence of testing and calibration Laboratories.
5. ISO/IEC 17011: 2004. Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies.
6. APLAC TC 008: APLAC Requirements and Guidance on the Accreditation of a Reference Material Producer Issue No. 4, Issue Date: 2013/08.
7. APLAC TC012 Guidelines for Acceptability of Chemical Reference Materials and Commercial Chemicals for Calibration of Equipment Used in Chemical Testing. Issue No. 2, Issue Date: 09/10.
8. ISO Guide 30: 1992. Terms and definitions used in connection with reference materials.
9. ISO Guide 30:1992/Amd.1: 2008 Revision of definitions for reference material and certified reference material.
10. ILAC G 12: 2000. Guidelines for the Requirements for the Competence of Reference Materials Producers.