Policies, Requirements and Conditions for Reference Material Producer Accreditation
Bureau of Laboratory Quality Standards, Department of Medical Sciences, Ministry of Public Health

1. Introduction

Bureau of Laboratory Quality Standards (BLQS) shall provide a high-quality accreditation and technical services to accredit reference material producer (RMP) comply with ISO 17034 in combination with the current version of the ISO Guides 31 plus ISO/IEC 17025 and/or ISO 15189. Our processes for such accreditation offer applicant bodies the opportunity to assure their customers or their customers of their compliance with the relevant international standards. Reference material producers (RMPs) 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 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 17011, *Conformity assessment - General requirements for the accreditation bodies accrediting conformity assessment bodies*, APAC and ILAC MRA requirement in order to have international recognition of the accreditation scheme. BLQS also uses the current version of the APAC TEC 008 – *APAC Guidance on Reference Material Use and Production* and the resulting Scope of Accreditation.

2. 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 of each type of RMP as well as the relevant standard (ISO) applied to each stage.

According to APAC TEC 008 – *APAC Guidance on Reference Material Use and Production*, the principles apply to the assessment and accreditations of RMPs are as follow:

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 Reference Materials (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.

2.2 The accreditation criteria shall be ISO 17034 and ISO/IEC 17025 and/or ISO 15189 in combination. A RMP shall meet all the requirements of these two documents that are relevant to its activities, before accreditation is granted. ISO 17034 is applicable to all active of RMP, including testing, calibration and measurement. The relevance of a requirement given in ISO 17034 and ISO/IEC 17025 and/or ISO 15189 should be assessed in the context of the activities performed rather than the organizational structure of the RMP facility.

2.3 A 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 APAC MRA Council resolved "that, within the context of the APAC 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 17034, clause 7.13)* and issues the RM documents and labels *(ISO 17034, clause 7.14)*; 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 17034 and ISO/IEC 17025 and/or ISO 15189 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 *(Table 1)* provides 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 17034 in combination with ISO/IEC 17025 and/or ISO 15189 and responsible organizations.

No.	Stages / Tasks of RM Production	Relevant ISO document
1.	Production Planning *	
2.	Selection of subcontractors (where relevant) *	
3.	Production control	
4.	Material handling, storage and processing	
5.	Assessment of homogeneity and stability *, **	ISO/IEC 17025 or ISO 15189
6.	Characterization and measurement of property values *, **	ISO/IEC 17025 or ISO 15189
7.	Assignment of property values and associated uncertainties *	
8.	Authorization of property values and associated uncertainties *	
9	Authorization of RM documents*	
10	Distribution	

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

* = 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 or ISO 15189

2.6 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.

b) 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.

c) 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.

d) An organization produces the candidate (C)RM and assigns the property values based on the measurement results from other (subcontractor) laboratories. Handling, storage and processing of the (C)RM are performed by the subcontractor. The certificate is issued by the producer.

e) An organization produces the candidate (C)RM and is responsible for the homogeneity and stability studies, for example. The property values are characterized and measured or operationally defined measurand by a NMI (National Measurement Institute) or an external accredited laboratory. The producer sells the (C)RM.

3. Scopes

3.1 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.

3.2 These requirements shall assure that 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.

3.3 The international Standard used for accreditation and the combinations of international standards are as follows:

3.3.1 ISO 17034:2016 General requirements for the competence of reference material procedures.

In-combination with:

3.3.2 ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories.

3.3.3 ISO 15189: 2012 Medical laboratories - Requirements for quality and competence

3.3.4 ISO Guide 30:2015 Selected terms and definitions.

3.3.5 ISO Guide 31:2015 Contents of certificates, labels and accompanying documentation.

3.3.6 ISO Guide 35:2017 Guidance for characterization and assessment of homogeneity and stability.

3.4 Stages / Tasks of RM production relevant to ISO 17034 in combination with ISO/IEC 17025 and/or ISO 15189 and responsible organizations. The range of property values for the (C)RMs with the associated uncertainties, where relevant, for which the RMP is accredited.

3.5 Categories and sub-categories of relevant materials are given in Appendix 1 which is a good guidance to describe the specific types of RMs for which a RMP is accredited.

3.6 The scope and certificate of accreditation shall state that the RMP meets the requirements of ISO 17034. There are relevant ISO/IEC 17025 and/or ISO 15189 requirements pertaining to every RMP assessment process, even if the RMP is only doing the tasks of production planning, selection of subcontractors, assigning and authorizing of property values associated uncertainties and (C)RM documents included issuing the certificate. A reference to ISO/IEC 17025 may, therefore also be included in each RMP's scope of accreditation for ISO 17034, i.e. the RMP meets the applicable requirements of ISO/IEC 17025 and/or ISO 15189 for the production of (C)RMs.

3.7 If the RMP requests accreditation as a laboratory to ISO/IEC 17025 and/or ISO 15189 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 (R 07 15 001).

3.8 As a RMP can do various tasks, 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.

4. Definitions

4.1 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.

4.2 Reference Material Producer Accreditation Committee

Reference Material Producer Committees are appointed by the Director of BLQS. The committee consists of technical experts in each discipline covering all scope categories of RMP accreditation and necessary authoritative bodies or stakeholders who are representatives

☞ from other organizations such as the National Institute of Metrology of Thailand (NIMT), technical experts in specific area of RM/CRM, RM user from the competent organization of government and private sectors, etc.

4.3 Certified Reference Material, CRM

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

4.4 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.

4.5 Certified value

Value, assigned to a property of a reference material that is accompanied by an uncertainty statement and a statement of metrological traceability, identified as such in the relevance material certificate.

4.6 Reference material document, RM document

Document containing all the information that is essential for using any reference material.

4.7 Traceability

The property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

4.8 Proficiency Testing, PT
Evaluation of participant performance against pre – established criteria by means of interlaboratory comparison.

4.8 Operationally defined measurand
Measurand that is defined by reference to a documented and widely accepted measurement procedure to which on results obtained by the same procedure can be compared.

☞ 4.9 Inter – laboratory Comparisons
Inter – laboratory Comparison is the organization, performance and evaluation of measurements or test under the predetermined conditions on the same or similar items by two or more laboratories for the accreditation submission according to the ISO/IEC 17025 and by three or more laboratories for the accreditation submission according to the ISO 15189.

☞ 4.10 Remote Assessment
Assessment of the physical location or virtual site of a conformity assessment body, using electronic means such as online environment allowing authorized persons to execute processes, e.g. in a cloud environment.

5. Qualification of the RMP applicants

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

6. General requirements

6.1 The top management of the RMP or the authorized representative shall sign the application ☞ forms and shall attached the evidence of authorizing representative documents enclosed with 30 Baht of revenue stamp.

6.2 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.

6.3 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.

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

6.5 The RMP shall corporate with the assessors in the following:

6.5.1 Permit the access to the premises.

6.5.2 Prepare for test sample and hand on analysis for witness as requested by the assessor.

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

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

6.7 In case of any amendment or any changes of the Policy, Requirements and Conditions BLQS shall inform the accredited RMP, via on BLQS website. The accredited RMP shall commit to follow such changes.

6.8 BLQS may reduce the scope or terminate the accreditation when if the RMP does not practice as described in clause 9, 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 Director of BLQS, the assessor, or the RMP accreditation committees.

6.9 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, to the director of BLQS. The RMP cannot refund fee for accreditation.

☞ 6.10. In case that an on-site assessment is not applicable, BLQS shall use another assessment technique to achieve the same objective as the on-site assessment being replaced and justified the use of such techniques e.g. remote assessment. For details on the requirements for remote assessment, please refer to the supplement requirements for document review and remote assessment, N 07 15 031.

7. Quality requirements

7.1 The RMP shall implement the requirements of ISO 17034 in combination with ISO/IEC 17025 or ISO 15189 and other relevant international standards including the policies, requirements and conditions of BLQS, DMSc.

7.2 The testing laboratory shall participate in proficiency testing program or inter-laboratory comparison as required by the policies, requirements and conditions of BLQS, DMSc (referred to N 07 15 003).

7.3 The RMP shall use and document the technically valid procedures to characterize its reference materials depend on the type of RMs, its matrix, its intended use, the analytical facilities and accredited scope of technical competence for the laboratories involved, and the capabilities of method employed, as mentioned in ISO Guide 35.

7.4 The RMP shall use procedures for assignment of property values and their uncertainties based on accepted statistical principles for assignment of property values as mentioned in ISO Guide 35.

☞ 7.5 The RMP shall conduct internal audit and review of management system at least once a year.

8. The Accreditation process

8.1 The RMP shall submit the application the BLQS with the listed document (Application form No. 11 (F 07 15 060), Application form No. 12 (F 07 15 061) and Application form No. 13 (F 07 15 062)). After the acceptance of the application, the BLQS will proceed as follows:

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

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

8.1.3 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 facility premise as pre-assessment. BLQS will inform the name of assessors and the date of pre-assessment before conduct the assessment.

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

8.1.5 The applicant RMP submits the corrective actions form (F 07 15 038) and evidences of the pre-assessment.

8.1.6 For the applicant RMP that was pre-assessed, the on-site assessment will be carried out after 60 days after per-assessed date, even if all of findings are not completely corrected.

8.1.7 In case that applicant RMP does not request for pre-assessment, the processes in the item 8.1.3 to 8.1.5 are omitted. BLQS will inform the name of the assessor and appoint the date of the on-site assessment. The applicant RMP shall pay an accreditation fee. The on-site assessment will be carried out.

8.1.8 BLQS inform the on site assessment results to the RMP by sending the official report of on site assessment.

8.1.9 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 applicant RMP shall propose a nonconformities corrective action table (F 07 15 038) and supportive evidences, both in the electronic and the current copy, to BLQS. The timescale of nonconformities corrective actions is mentioned for each of assessment type as following:

8.1.9.1 **For pre-assessment,** the applicant RMP shall submit the corrective actions within 30 day after pre-assessed date. In case that the RMP cannot complete the corrective actions within 30 days, the RMP may extend the duration of corrective actions for another 30 days, in written, to the Director the BLQS, with the reason and the approximate date for completion of corrective actions.

8.1.9.2 **For on site assessment of new accreditation,** the RMP shall submit the corrective actions within 90 days after assessed date. In case that the RMP cannot complete the corrective actions within time frame, the RMP can request for extended the period of time for corrective action, in written, to the Director of BLQS with the reason and the approximate date for completion of corrective actions. However, the timeframe of corrective actions and closed out shall be done within 120 days after the date of closing meeting for the assessment. If the RMP carried out the corrective actions longer than 120 days, the scope of accreditation which have not been corrected and closed out within timeframe will be withdrawn or rescinded.

8.1.9.3 **For follow up or extra ordinary follow up,** the RMP shall submit the corrective actions within 15 days. If the RMP cannot complete the corrective actions within the time frame given, BLQS shall reduce the scope of accreditation which does not complete of corrective actions. All expenses are the responsibility of the RMP.

8.1.9.4 **For surveillance, reassessment and extended scope of the accreditation,** the RMP shall carry out the corrective actions of nonconformity within 30 days after assessed date. In case that the RMP cannot complete the period of time for corrective

actions for 30 days, in written, to the Director of BLQS with the reason and the approximate data for completion of corrective actions within 30 days of extension. If the RMP cannot complete and closed out the corrective actions 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.

8.1.10 BLQS will issue the certificate of accreditation after the Reference Material Producer Accreditation Committee grants the accreditation approval. The certificate of accreditation signed by the Director of BLQS-DMSc.

8.2 The accreditation certificate is valid for 4 years from issued date and accredited RMP can verify its valid date from the certificate and on the BLQS-DMSc website (http:blqs.moph.go.th).

8.3 In case of accreditation certificate is lost, the RMP can file for request a replaced one. Both of the governmental or private laboratories shall submit the official request memorandum to the Director of BLQS-DMSc enclosed with the police report for lost document within 15 days of the incident date. Payment shall be following as fee schedule determined by BLQS-DMSc.

8.5 In case of damaged accreditation certificate, the RMP can file for request a replaced one. The laboratories shall submit the official request memorandum to the Director of BLQS-DMSc enclosed with the damaged certificate. Payment shall be following as fee schedule determined by BLQSDMSc.

8.6 In case of accreditation certificate is needed to edit by the RMP, they shall submit the official request memorandum to the Director of BLQS-DMSc enclosed with the edited remark of application form, evidence, principle reference, and reasonable description for non – significance changes from previous assessment. Editorial of accreditation certificate will be processed and the RMP shall paid for new accreditation certificate regarding to the current announcement of DMSc.

9. Practices for the accredited RMP:

9.1 Maintains quality management system compliance to the accreditation certificate of the international standard of ISO 17034 and/or ISO/IEC 17025 and/or ISO 15189 in combination with and BLQS policies, requirements and conditions at all time of accreditation.

9.2 Cooperate to enable BLQS to verify fulfilment of requirements for accreditation.

9.3 Provide access to personnel, locations, equipment, information, documents and records as necessary for the assessment and maintenance of the accreditation.

9.4 Provide access to the information of independence level and impartiality of the RMP from its related bodies, where appropriable.

9.5 Arrange the witnessing of RMP services as requested.

9.6 Have, where applicable, legally enforceable arrangements with their customers that commit the customers to provide, on request, access to BLQS assessment teams to assess the RMP performance when carrying out RMP activities at the customer's site.

9.7 Optionally uses the BLQS accreditation symbol or accreditation statements. In both cased, the accredited RMP shall in form BLQS the intension to use the BLQS accreditation symbol or accreditation statements as mentioned in N 07 15 009.

9.8 Correctly uses the BLQS accreditation logos/symbols or statements. BLQS will take necessary actions against the accredited RMP or individuals who misused any of the BLQS accreditation logos/symbols or statements in the way of incorrect references or misleading or misrepresentation, for example using BLQS accreditation symbol for unaccredited test or unauthorized approved signatory. In these cases, the accredited RMP shall be suspended of accreditation for 90 days and might be sentenced by law.

9.9 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 and associated consequence without undelay.

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

9.11 Shall inform BLQS, within 15 days, if there is any change from the application forms, such as:-

9.11.1 Legal status or business status and organization chart.

9.11.2 Top management who make a decision for the organization management.

9.11.3 Policy and activities conducted by the accredited RMP.

9.11.4 Personnel, equipment, environment that have an effect directly to the RMP.

9.11.5 Approved signatories for the accredited RMP.

9.11.6 The claim or the use of BLQS accreditation symbol.

9.11.7 Others changes that may affecting the competence of the RMP.

9.12 Pay fees as determined by BLQS – DMSc.

9.13 Shall assist BLQS to provide the facts in the investigation and resolution of any complaints made by third parties or interested parties on the RMP's accredited scope.

☞ 9.14 Collection and storage of all quality documents for at least 5 years, therefore, the documents can be traceable on various media such as hard copy or electronic means.

10 Surveillance

☞ 10.1 Surveillance assessment for the accredited RMPs shall done as follows:

10.1.1 On-site surveillance assessment shall be carried out at interval within 2 years after the last day of the initial assessment. The accredited RMP shall submit the quality documents for surveillance assessment to the BLQS in advance, at least 120 days of surveillance schedule and shall pay for surveillance fee as indicated. A second assessment shall be established within 60 days prior to surveillance schedule. The accreditation RMP may by suspended of accreditation if there is any evidence indicates that the accredited RMP cannot maintain their quality management system.

10.1.2 Another surveillance shall be done, if it is the decision making from the RMP accreditation committees, or as a result of complaint, or there is indicates the accredited RMP cannot maintain their quality management system.

11. Reassessment

☞ 11.1 Reassessment shall be taken place at intervals not exceeding than 4 years after the last date of the initial assessment. Accredited RMP shall submit the quality document to BLQS in advance, at least 120 days of on-site reassessment schedule without BLQS-DMSc notification. The renewal assessment shall be established within 60 days prior to on-site reassessment schedule. Failure to meet this condition shall be

considered as the RMP does not intend to reaccredit. The accreditation will be ended up as the expiration date on the certificate.

☞ 11.2 Accredited RMP shall submit the complete documents for reassessment with reassessment application forms to BLQS in advance, and shall pay for accreditation fee as indicated. The reassessment shall be taken place at intervals not exceeding 4 years after the last day of the initial assessment.

12. 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:

☞ 12.1 The accredited RMP shall apply for extension scope of accreditation at the same time of re-assessment and pay for accreditation fee as indicated, and the laboratory shall submit the document for extended scope and re-assessment according to clause 8.1. If the RMP submitted the document for extended scope to be late from the timeframe given for re-assessment, the BLQS-DMSc shall appoint the assessors for re-assessment only. The extended scope shall be separate laboratory and the laboratory shall pay for accreditation fee as indicated.

☞ 12.2 In case that accredited RMP needs to apply for extension scope of accreditation before the time of reassessment, it can request an extension to scope at any time. The accredited RMP shall submit all of application forms No. 11, No. 12 and No. 13 together with the related quality documents to BLQSDMSc. The BLQS-DMSc shall carry out the on-site extension in the same manners as in the initial assessment. The RMP shall pay for accreditation fee as indicated. The expiry date of certificate for extension scope shall be the same expiry date of previous certificate.

13. Withdrawal / Suspension of the accreditation

13.1 Withdrawal of the accreditation:-

The Director of BLQS, DMSc will withdraw the accreditation under the following circumstances.

13.1.1 The RMP has become bankruptcy by court order.

13.1.2 Any practice that violate or do not comply with the Act for "Thai National Standards" B.E. 2551 *(National standards Act, B.E> 2551 (2008). Published in The Royal Thai Government Gazette. Volume 125, Part 42 A, Published Date 4th March A.D. 2008)* and the BLQS policies, requirements and conditions.

13.1.3 The RMP terminates its business.

13.1.4 If there is evidence of fraudulent behavior, intentional provision of false information or conceals information

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

13.2 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 nonconformities within a given timeframe, if the accredited RMP cannot correct and closed out the nonconformities within a given timeframe again, BLQS will withdraw or reduce the scope of the accreditation, accordingly.

☞ 13.3 Voluntary Withdrawal

The accredited RMP can request for withdraw from the accreditation program by officially inform the Director of BLQS and shall not use or claim BLQS-DMSc accreditation symbol or reference to its accredited status for the activities.

14. Confidentiality

14.1 All information provide by any applicants in relation to preliminary enquiries or to an application for accreditation and all information obtained in the scope of, or in connection with, and assessment of an accredited RMP shall be confidential.

14.2 BLQS-DMSc shall not disclose confidential information about a particular accredited RMP without written concern of the accreditation RPM, except where the law requires such information to be disclosed without such consent. All personnel, assessors and committee of BLQS shall be aware of and by this requirement for confidentially. They are required and sign the formal undertaking for maintain confidentially and impartiality and declaration of conflict of interest.

15. Appeal

15.1 The BLQS-DMSc established guideline for appeals of RMP as indicated in G 07 15 007.

15.2 The appeal for any decisions shall be submitted in written to the Chairman of the Appeal Committee within 15 days upon receipt of the withdrawal letter.

15.3 The decision of Appeal Committee shall process within at 3 months period.

15.4 The decision of Ad-hoc Appeal Committee for RMP's decision is a final.

15.5 During the appeal, the accreditation is still valid.

16. Use of accreditation symbol

16.1 The accredited RMP shall inform the using of the accreditation symbol or accreditation statement as defined in the BLQS policy, requirements and conditions for using of accreditation symbol or accreditation statement (referred to N 07 15 009).

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

16.3 The symbol shall not be abused, misused, or misleaded in the accreditation. Misused of those symbols to their accreditation status or in any form of the BLQS policies, requirements and conditions may be also legal penalties. The accredited RMP shall be suspended of accreditation, may be punished according to the law.

17. Miscellaneous

17.1 BLQS will inform any changes in the requirements and conditions on BLQS-DMSc website (http://blqs.dmsc.moph.go.th), which shall be corrected and adjusted within the timeframe.

17.2 BLQS may investigate any complaint made to BLQS by the third parties against an accredited RMP concerning activities included in its scope of accreditation. The RMP shall provide information to BLQS upon request and shall cooperate with BLQS for the purpose of investigating the complaints.

17.3 BLQS reserves the right not to disclose any complainant.

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

17.5 BLQS shall not be liable to the accredited RMP for any losses, damages or expenses including injury to reputation suffered by the accredited RMP and third parties, arising directly or indirectly from the accreditation of the accredited RMP, use of the accreditation symbol, assessment activities carries out on the accredited RMP by BLQS, its representatives and employees except if such loos or damage results from negligence by BLQS.

17.6 The accredited or suspended or withdrawn RMP names, tests, method and accreditation number will be announced in the website: http://blqs.dmsc.moph.go.th

17.7 Interested party shall submit the application to BLQS, DMSc, within the Ministry of Public Health (MOPH), Nonthaburi.

17. History of change

Revision No.	Documentation Change	Prepared / Revised by	Date Issued
00	Initial document	Ms. Waraporn Piyasirananda	22 Nov 2013
02	Withdraw references according to *ILAC Resolution 18.18* as follows: - ILAC G12:2000 - ILAC G9:2005 Update international standard requirements according to current version as follows: - ISO 17034:2016 - APLAC TC 008:2015 - ISO Guide 30:2015 - ISO Guide 31:2015	Mr. Awiruth Khejonnit	4 Nov 2017
03	Update references according to current version and related details as follows; - APAC TEC 008 - ISO Guide 35:2017 - ISO 15189:2012 Update stages or tasks of RM production relevant to ISO 17034:2016 in clause no.2 Update and added details in definitions clause no. 4.2 to 4.8 Update and added details and relevant information regarding to BLQS policy and requirements (R 01 15 001) as following; - Accreditation process in clause no. 8.1.9.5, 8.2, - Practices for the accredited RMP in clause no. 9.2 to 9.6, 9.12, 9.13, - Reassessment in clause no. 11.1, - Extension scope of accreditation in clause no. 12.2, - Withdrawal/Suspension of accreditation in clause no. 13.1.4, - Miscellaneous in clause no. 17.	Mr. Awiruth Khejonnit	22 October 2019

Revision No.	Documentation Change	Prepared / Revised by	Date Issued
04	Added information; - clause no. 4.9, definition of Inter – laboratory comparisons. - Clause no. 4.10, definition of Remote Assessment. - Added details of the evidence of representative documents of authorized person of RMP. - Clause no. 6.10, alternative technique for assessment. - Clause no. 7.5, requirement for internal audit and management review of RMP. - Clause no. 8.1.9.2, process of withdraw scope of accreditation in case of corrective actions cannot closed out within timeframe. - Clause no. 8.3, process of issuing new certificate in case of it is lost or damaged. - Clause no. 8.4, process of issuing new certificate in case of editorial is needed. - Clause no. 13.3 Voluntary withdrawal - Clause no. 15.1, Guideline for Appeals Updated details for new accreditation RMP in clause no. 8.1.9.2 Updated validity of accreditation certificate from 2 years to 4 years regarding to BLQS policy in clause no. 8.2. Updated for storage of RMP quality documents from 3 years to 5 years in clause no. 9.14 Updated details of surveillance in clause 10.1 and 10.2 Updated details of reassessment in clause no. 11.1 Updated details of extension scope of accreditation in clause no. 12.2 Updated details of miscellaneous in clause no. 17.1 Deleted clause no. 17.8 annual fee was canceled.	Mr. Awiruth Khejonnit	

APPENDIX 1

Category A: Chemical composition

Reference materials, being either pure chemical compounds or representative sample maple 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 characterized 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 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

A2: INORGANIC REFERENCE MATERIALS

A2.6 Pure chemicals

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

A3: ORGANIC REFERENCE MATERIALS

A3.1 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
amphentamine
Methylamphetamine
3, 4-methylenedioxyamphetamine

3, 4-methylenedioxy methylamphetamine
3, 4-methylenedioxy ethylamphetamine
diacetylmorphine
morphine
cocaine
lysergic acid diethyamide 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

A3.3 Foodstuffs

Proximate analysis
Nutritional properties
Vitamins
Other food additives
antioxidants
emulsifiers
Trace elements
Trace organics
Pesticide residues
Other organic contaminants

A5: HEALTH AND INDUSTRIAL HYGIENE

A5.1 Clinical laboratory materials
A5.2 Ethanol solutions

A8: FORENSIC REFERENCE MATERIALS

A8.1 Ethanol reference standards
Ethanol
Ethanol, aqueous solutions containing 0.050, 0.150, 0.250 g/100mL

A9: ION ACTIVITY

A9.1 pH standards
A9.2 Ion selective electrode calibrants
A9.3 Conductivity standards
A9.4 Buffer systems

CATEGORY B: BIOLOGICALAND CLINICAL PROPERTIES

B1: General Medicine
- B1.1 Human serum materials (powder and solution forms)

B2: Clinical Chemistry
- B2.1 Proteins
- B2.2 Apolipoproteins
- B2.3 Enzymes
- B2.4 Hormones
- B2.5 Trace elements
  - Lead and cadmium

B3: Tissue Pathology

B4: Haematology and Cytology
- B4.1 Blood serum

B5: Immunohaematology

B6: Immunology

B7: Parasitology

B8: Bacteriology and Mycology
- B8.1 Reference cultures
- B8.2 Antibiotics

B9: Virology

B10: Other biological and clinical reference materials

B11: Forensic Reference Materials
- Purified DNA of known and continuing genetic composition
- Human, primate and animal blood
- Animal hairs

CATEGORY E: MISCELLANEOUS PROPERTIES

(Sub-categories to be developed as required).

Controlled Copy List

1	Director Bureau of Laboratory Quality Standards (BLQS)	Code No. 07 00
2	Head of Laboratory Accreditation Section 1	Code No. 07 03
3	Head of Laboratory Accreditation Section 2	Code No. 07 04
4	Quality Manager of Laboratory Accreditation	Code No. QCC 07
5	Mr. Awiruth Khejonnit	