Policies, Requirements and Conditions for Reference Material Producer Accreditation

1. Introduction

Bureau of Laboratory Quality Standards (BLQS) shall provide a high-quality accreditation and technical services to accredit reference material producer (RMP) complies 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 authorities to operate all activities independently. The accreditation shall be impartial among all organizations, both with internal and external agencies of DMSc.

BLQS shall ensure the accreditation system of RMP complies with ISO 17011, *Conformity assessment - General requirements for the accreditation bodies accrediting conformity assessment bodies,* APAC, and ILAC MRA requirements, in order to have international recognition of the accreditation scheme. BLQS also uses the current version of the APAC TEC1-008 – *APAC Guidance for accreditation of Reference Material Producers (RMPs)* and the resulting Scope of Accreditation.

2. Types of RMP

Reference Material Producer contains many stages of activities (tasks of RMP), some of which can be subcontracted. The types of RMP are classified by the number of tasks 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 TEC1-008 – *APAC Guidance for accreditation of Reference Material Producers (RMPs)*, the principles that apply to the assessment and accreditation of RMPs are as follows:

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 a "laboratory” solely. 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 an 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 the provision of reference values to a candidate RM, it cannot be considered an RMP.

2.2 The accreditation criteria shall be ISO 17034 and ISO/IEC 17025 and/or ISO 15189 in combination. An 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 activities of RMP, including testing, calibration, and measurement. The relevance of a requirement given in ISO 17034, 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 that 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 regarding these tasks shall be made by the RMP.

** = Testing, calibration, and measurement activities involved in reference 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 as a measurand by an NMI (National Measurement Institute) or an external accredited laboratory. The producer sells the (C)RM.

3. Accreditation scope

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, and assignment of property values to the materials, including stability and homogeneity, which are then factored into the Reference Material Procedures uncertainty reported.

3.3 The international standards 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 15189:2022 Medical laboratories - Requirements for quality and competence

3.3.4 ISO Guide 30:2015 Selected terms and definitions.

3.3.5 ISO 33401:2024. Reference materials - Contents of certificates, labels, and accompanying documentation.

3.3.6 ISO/TR 33402:2025. Good practice in reference material preparation.

3.3.7 ISO 33403:2024. Reference materials – Requirements and recommendations for use.

3.3.8 ISO 33405:2024. Reference materials – Approaches for characterization and assessment of homogeneity and stability.

3.3.9 ISO 33406:2024. Approaches for the production of reference materials with qualitative properties.

3.3.10 ISO 33407:2024. Guidance for the production of pure organic substance certified reference materials.

3.3.11 ISO 33408:2025. Guidance for the production of pure inorganic substance certified reference materials.

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 guide to describe the specific types of RMs for which an 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 with uncertainties, and (C)RM documents, including 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 an RMP can do various tasks, accreditation shall be granted to it for those activities that have 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 an 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 competent 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 areas of RM/CRM, RM users from the competent organization of government and private sectors, etc.

4.3 Certified Reference Material, CRM

Reference material (RM) is 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.

4.9 Operationally defined measurand

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

4.10 Inter – laboratory Comparisons

Inter – laboratory Comparison is the organization, performance, and evaluation of measurements or tests 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.

4.11 Remote Assessment

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

5. Qualification of the RMP applicants

The RMP must be legally identifiable. All practices shall comply with Thai laws and regulations. For cross-border accreditation, the laws and regulations of a certain country must be complied 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 attach the evidence of the authorizing representative documents enclosed with 30 Baht of revenue stamp.

6.2 Each applicant must nominate a senior staff member who will represent them 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 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 the fee as scheduled and conditioned by BLQS.

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

6.5.1 Permit access to the premises.

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

6.5.3 Assist and allow the use of the office stationery 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 work.

6.7 In case of any amendment or any changes to the Policy, Requirements, and Conditions, BLQS shall inform the accredited RMP via the BLQS website. The accredited RMP shall commit to following such changes. BLQS shall inform CABs of any changes via the official website (https://blqs.dmsc.moph.go.th/page-view/6 2 6). Notify the public of updates to the specifications document on the website. In the event of technical accessibility issues, BLQS shall ensure direct delivery via email or secure file-sharing platforms (e.g., Google Shared Drive, OneDrive).

6.8 BLQS may reduce the scope or terminate the accreditation if the RMP does not practice as described in clause 9, or there is any indication to demonstrate that the scope of accreditation does not comply 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 the applicant RMP is in the process of accreditation or has already been accredited by the BLQS and the RMP intends to withdraw the accreditation, the RMP shall inform the BLQS, officially, in writing, to the director of BLQS. The RMP cannot refund the 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 justify 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 a 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 the method employed, as mentioned in ISO 33405 (quantitative) and ISO 33406 (qualitative).

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 33405.

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

8. The Accreditation process

8.1 The RMP shall submit the application to the BLQS with the listed documents (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 informs the applicant to pay the fee as indicated by BLQS.

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

8.1.3 Pre-assesses, if it is required by the applicant, the RMP is notified of the date, time, and the assessor's name. The assessors will assess the QA manual and related documents at the facility premises as a pre-assessment. BLQS will inform the names of assessors and the date of pre-assessment before conducting the assessment.

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

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

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

8.1.7 In case the applicant RMP does not request a 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 informs the on-site assessment results to the RMP by sending the official report of the on-site assessment.

8.1.9 The RMP shall correct all nonconformities within the timescale of the requirements for the accreditation process of the BLQS. The duration for corrective action begins on the date of the closing meeting for the assessment. The applicant RMP shall propose a nonconformities corrective action table (F 07 15 038) and supportive evidence, both in the electronic and the current copy, to BLQS. The timescale of nonconformity corrective actions is mentioned for each of the assessment types as follows:

8.1.9.1 **For pre-assessment,** the applicant RMP shall submit the corrective actions within 30 days after the pre-assessment date. In case the RMP cannot complete the corrective actions within 30 days, the RMP may extend the duration of corrective actions for another 30 days, in writing, to the Director of 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 the assessment date. In case the RMP cannot complete the corrective actions within the time frame, the RMP can request an extension of the period of time for corrective action, in writing, to the Director of BLQS with the reason and the approximate date for completion of corrective actions. However, the timeframe for corrective actions and closing out shall be done within 120 days after the date of the closing meeting for the assessment. If the RMP carried out the corrective actions longer than 120 days, the scope of accreditation that has not been corrected and closed out within the 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 until corrective actions. All expenses are the responsibility of the RMP.

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

for corrective actions within 30 days, in writing, to the Director of BLQS with the reason and the approximate date for completion of corrective actions within 30 days of extension. If the RMP cannot complete and close 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 renew 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 was signed by the Director of BLQS-DMSc.

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

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

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

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

9. Obligation for the accredited reference material producer

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 the BLQS policies, requirements, and conditions at all times of accreditation.

9.2 Cooperate to enable BLQS to verify fulfillment 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 on the independence level and impartiality of the RMP from its related bodies, where appropriate.

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 cases, the accredited RMP shall inform BLQS of the intention 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 misuse any of the BLQS accreditation logos/symbols or statements in any way, including incorrect references or misleading or misrepresentations. For example, using the BLQS accreditation symbol for an unaccredited test or an unauthorized approved signatory. In these cases, the accredited RMP shall be suspended from 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 in scope of accreditation. Such misuses might result in legal responsibility. The accredited RMP shall inform its customer of its accredited status and associated consequences without delay.

9.10 Shall not do anything which may mislead that the granted accreditation is BLQS certification for non – accredited scopes.

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's management.

9.11.3 Policy and activities conducted by the accredited RMP.

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

9.11.5 Approved signatories for the accredited RMP. If the RMP loses its sole approved signatory for more than three months, the accreditation status of the RMP will be suspended.

9.11.6 The claim or the use of the BLQS accreditation symbol.

9.11.7 Other changes that may affect 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 and follow-up

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

☞ 10.1.1 Surveillance assessment shall be carried out at interval within two years since the accreditation date was issued. The accredited RMP shall submit the quality documents for surveillance assessment according to application form No. 12, F 07 15 061, to the BLQS in advance, at least seven months before the surveillance schedule, and shall pay for the surveillance fee as indicated. Then the assessment shall be established within 5 months before the certificate reaches two years of age, in order to ensure that the surveillance activity is completed within two years of the initial accreditation. The accreditation RMP may be suspended if there is any evidence that indicates that the accredited RMP cannot maintain its quality management system.

10.1.2 Follow-up or extraordinary follow-up shall be done if it is the decision of the RMP accreditation committees, or as a result of a complaint, or if it indicates the accredited RMP cannot maintain its quality management system.

11. Re-assessment

11.1 Re-assessment shall take place at intervals not exceeding 4 years. Accredited RMP shall ☞ submit the quality document to BLQS in advance, in the fourth year from the date of accreditation, the accredited RMP shall apply for renewal of accreditation at least seven months before the expiry date of the certificate, and the renewal assessment shall be conducted at least five months before the expiry date, to ensure that the renewal process is completed no later than the certificate expiry date of accreditation certificate. 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 re-assessment with application forms to BLQS in advance, and shall pay the accreditation fee as indicated. The re-assessment shall take place at intervals not exceeding 4 years.

12. Extension scope of accreditation (Extending accreditation)

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

12.1 The accredited RMP shall apply for extension of the scope of accreditation at the same time as surveillance and re-assessment and pay for the accreditation fee as indicated, and the RMP shall submit the document for the extended scope and surveillance or 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 schedule, and the RMP shall pay for the accreditation fee as indicated.

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

13.1.2 Any practice that violates or does 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 concealment of information

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

13.2 Voluntary Withdrawal

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

13.3 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.

14. Confidentiality

14.1 All information provided 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 the written consent, except where the law requires such information to be disclosed without such consent. All personnel, assessors, and the committee of BLQS shall be aware of and adhere to this requirement for confidentiality. They are required to sign the formal undertaking to maintain confidentiality and impartiality, and a declaration of conflict of interest.

15. Appeal

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

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

15.3 The decision of the Appeal Committee shall be processed within at 3 months period.

15.4 The decision of the Ad-hoc Appeal Committee for RMP’s decision is final.

15.5 During the appeal, the accreditation is still valid.

16. Use of accreditation symbol

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

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

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

17. Miscellaneous

17.1 BLQS will inform of any changes in the requirements and conditions on the BLQS-DMSc website (https://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 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, suspended, or withdrawn RMP names, tests, method, and accreditation number will be announced on the website: https://blqs.dmsc.moph.go.th

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

18. Responsibility of the assessment report reviewer committees and the accreditation committees.

18.1 The responsibility of the assessment report reviewer committees is as follows;

18.1.1 To review the assessment report of RMP complying with ISO 17034 and the policy, requirements, and conditions for the accreditation before proposing the RMP accreditation committee.

18.1.2 To delegate others' missions.

18.2 The responsibilities of the RMP accreditation committees are as follows;

18.2.1 To approve the grant of RMP accreditation with ISO 17034 and the policy, requirements, and conditions for the accreditation.

18.2.2 To approve the withdrawal of the RMP accreditation in case the RMP is out of business, has become bankrupt by court order, or any practice that violates or does not comply with the BLQS-DMSc requirements.

18.2.3 To delegate other missions.

19. Supplementary note

Appendix 1: Submitted documents for accreditation application are as follows;

☞ 19.1 Application Form No. 11 [F 07 15 060] – RMP Application Form No. 11 for ISO 17034:2016 Accreditation (A Request and Specific Information).

19.2 Two sets of location maps of the laboratory and nearby landmark buildings.

19.3 Copy of the certificate of registration as a legal entity with registration purpose, and the trade registration of the commercial registration.

19.4 Copy of the trade registration of the company registration.

19.5 Power of attorney for the applicant. The evidence of the authorizing representative is enclosed with 30 Bath of revenue stamps.

19.6 Copy of identification of the applicant (For foreign RMP).

19.7 Application Form No. 13 [F 07 15 062] – Documents accompanied the RMP accreditation application of conformity assessment body (CAB).

19.8 Nominate a senior staff member as a representative in all dealings with BLQS-DMSc. This person shall take responsibility for communication between top management / within the organization or laboratory, and BLQS-DMSc.

Appendix 2: Example of reference materials categories, but not limited to, are as follows;

Chemical composition: Reference materials, being either pure chemical (organic and inorganic) 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.

Biological and clinical properties: Materials similar to Category A, but characterized by one or more biochemical or clinical property values.

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

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.

19. 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 the 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 the current version and related details as follows; - APAC TEC 008 - ISO Guide 35:2017 - ISO 15189:2012 Update stages or tasks of RM production	Mr. Awiruth Khejonnit	22 October 2019

Revision No.	Documentation Change	Prepared / Revised by	Date Issued
	relevant to ISO 17034:2016 in clause no.2 Update and added details in the definitions clause no. 4.2 to 4.8 Update and added details and relevant information regarding BLQS policy and requirements (R 01 15 001) as follows; - 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.		
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 the 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, the process of	Mr. Awiruth Khejonnit	3 August 2021

Revision No.	Documentation Change	Prepared / Revised by	Date Issued
	withdraw scope of accreditation in case of corrective actions cannot be closed out within the timeframe. - Clause no. 8.3, process of issuing a new certificate in case it is lost or damaged. - Clause no. 8.4, process of issuing a new certificate in case of an editorial is needed. - Clause no. 13.3 Voluntary withdrawal - Clause no. 15.1, Guideline for Appeals Updated details for the new accreditation RMP in clause no. 8.1.9.2 Updated validity of accreditation certificate from 2 years to 4 years regarding the 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 clauses 10.1 and 10.2 Updated details of reassessment in clause no. 11.1 Updated details of the 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.		
05	- Updated document format aligned to the current standard operating procedure of	Mr. Awiruth Khejonnit	4 March 2024

Revision No.	Documentation Change	Prepared / Revised by	Date Issued
	BLQS. - Updated the current edition of references ISO 15189:2022. - Added clause 17; Responsible for the assessment report reviewer committee and the accreditation committees. - Added clause 18; Supplementary note [Appendix 1 and 2].		
06	- Clause no.1 and no. 2, updated current version of the APAC TEC1-008. - Clause no. 3, updated references and guidance related to the implementation of RMP regarding ISO standards of ISO 3340x series. - Clause 7.4, added ISO 334.6; reference for the production of reference materials with qualitative properties. - Clause 8.1.3, edited to replace the word “laboratory” with “RMP” for consistency of content. - Clause 11.1 added more details for the reassessment process. - Appendix 2 deleted list of examples of RM/CRM.	Mr. Awiruth Khejonnit	15 December 2025
07	- Clause 6.7, added alternative ways of communication to the CAB other than the website, in case of the event of technical accessibility issues is unauthorized, BLQS shall ensure direct delivery via email or secure file-sharing platforms (e.g., Google Shared Drive, OneDrive).	Ms. Waraporn Piyasirananda	Mar 2026

Revision No.	Documentation Change	Prepared / Revised by	Date Issued
	- Clause 10.1 and 11.1, change the timeframe for submitting documents for surveillance and reassessment to 7 months prior. - Clause 19.7, cancel the application form No. 12 [F 07 15 061 – RMP specific information for accreditation] as it has already been included in the Application Form No. 11 [F 07 15 060 – A request for Reference Material Producer]. - Clause 19.1, change the name of Application Form No. 11 [F 07 15 060 (T)] to RMP Application Form No. 11 for ISO 17034:2016 Accreditation (A Request and Specific Information)		