Policies, requirements and conditions for a medical and health laboratory accreditation

1. Accreditation scope

1.1 Type of Laboratory

1.1.1 Health Laboratory or Consumer Protection Laboratory (Health products testing)

1.1.2 Forensic Laboratory

1.1.3 Veterinary Laboratory

1.1.4 Medical Laboratory

1.2 Test method

1.2.1 Legal method approved for testing of the product's quality

1.2.2 International recognized standard method

1.2.3 Customer requirement method

For test methods that are in-house or modified from a standard method, there shall be documents on details of the validation procedure and documents on details of the test method.

2. Definitions and abbreviation

2.1 Accreditation.

Procedure that the BLQS-DMSc gives formal recognition that the conformity assessment body (CAB) or laboratory has the management to comply with the related international standard and policy, requirements, and conditions for laboratory accreditation of BLQS-DMSc and CAB competence to carry out specific tasks listed in the scope of accreditation.

2.2 Laboratory Accreditation Committee (LAC)

Laboratory accreditation committee for public health laboratory and laboratory accreditation committee for medical laboratory are responsible for granting of accreditation.

2.3 Assessment Report Reviewer

Assessment report reviewer for public health laboratory and medical laboratory is responsible for reviewing, evaluating and approving a summary report of assessment from assessor before proposing to the LAC.

2.4 Health products

Health products are related to health, biological products, radiation, medical devices, and medical products, which are under the responsibility of the Ministry of Public Health (MOPH) such as foods, pharmaceuticals, narcotics, cosmetics, herbals, and hazardous substances.

2.5 Forensic laboratory

The laboratory is multi-disciplinary testing in forensic sciences. The forensic samples are collected from human specimens, toxic substances, chemical materials that can hazard to human, or other evidence samples. These test results are for supporting the court case consideration.

2.6 Veterinary laboratory

Laboratory carried out diagnostic and clinical veterinary laboratories that conduct commercial, government, academic, and international veterinary testing.

2.7 Medical laboratory

The laboratory is multi-disciplinary testing in medical area. The test result is using for diagnosis, controlling and prevention of disease. In addition, medical testing is covered the interpretation, consultation, investigation and medical research study.

2.8 Proficiency Testing (PT)

Proficiency testing (PT) is the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

2.9 Interlaboratory Comparison

Interlaboratory 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 ISO/IEC 17025 and by three or more laboratories for the accreditation submission according to the ISO 15189.

2.10 Remote assessment

Remote assessment of the physical location or virtual site of a conformity assessment body, using electronic means.

Note 1: A virtual site is an online environment allowing persons to execute processes, e.g. in a cloud environment.

3. Qualification of the laboratory applicant

The laboratory must be legal entity or a defined part of a legal entity such that it is legally responsible for its laboratory activities. The laboratory may comprise permanent laboratory facilities, with or without sites away from its permanent or in associated temporary or mobile facilities. It must not be a laboratory that had been withdrawal, unless more than six months after withdrawal.

4. General requirement

4.1 The authorized director of the laboratory or the authorized representative shall sign the application form. The laboratory shall attach the evidence of authorizing representative and enclosed with 30 baths of revenue stamp.

4.2 Each applicant must nominate a senior staff member who will represent one in all nominations in all dealings with BLQS-DMSc. This person shall take responsibility for communication between top management / within the organization or laboratory, and BLQS-DMSc. The BLQS-DMSc shall not take any responsibility for any dealings with top management / within the organization or laboratory, and BLQS-DMSc.

4.3 All details of the quality management system and the implementation document, which are fulfill the requirements of the BLQS-DMSc, shall be submitted with a current copy and electronic file which easily search identical name file. BLQS-DMSc will terminate the application if the documents are not completed within 60 days, after the date of submitting the application. The laboratory cannot refund fee for accreditation.

4.4 The laboratory shall comply with the accreditation procedure and shall pay fee as scheduled and conditioned by BLQS-DMSc.

4.5 The laboratory shall corporate with the assessors in the following: -

4.5.1 Permit the access to the laboratory personnel, locations, equipment, information, document and records.

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

4.5.3 Assist and allow the use of the office stationery and the communication apparatus as necessary

4.5.4 Responsible for the travel and accommodation expenses of the assessors according to the actual expenses both on-site assessments of the laboratory and remote assessment.

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

4.7 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.

4.8 BLQS shall inform CABs and interested parties of any changes to its accreditation policies and requirements through its official website (https://blqs.dmsc.moph.go.th/page-view/626). In cases where cross-border technical constraints or firewalls prevent access to websites, BLQS shall ensure the direct delivery of essential documents via email or synchronized file-sharing services (e.g., Google Shared Drive, OneDrive, or designated digital platforms). All accredited CABs are required to acknowledge and implement these revised requirements accordingly.

4.9 BLQS-DMSc may reduce the scope or terminate the accreditation when if the laboratory does not perform as described in clause 7. (Obligations for the accreditation laboratory) 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 or assessment report reviewer or the laboratory accreditation committees.

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

5. Quality requirement

5.1 The laboratory shall implement the quality management system according to the ISO/IEC 17025 or ISO 15189 or ISO 15189 plus with ISO 15190 or other relevant standards, accordingly.

5.2 The laboratory shall participate in proficiency testing program (s) or inter-laboratory comparison or laboratories performance assessment as required by the Policy, Requirements and Conditions of the BLQS-DMSc. For details

on the requirements for proficiency testing, please refer to the Policy and requirements for Proficiency Testing, interlaboratory comparison/Laboratories performance assessment in test, N 07 15 003.

5.3 The laboratory shall conduct internal audit and review its management system at least once a year.

6. The accreditation process

6.1 The laboratory shall submit the application to the BLQS-DMSc with the listed of relevant documents as mentioned in Appendix 1 and 2.

6.2 After the acceptance of the application, the BLQS-DMSc will proceed as following:

6.2.1 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-DMSc. BLQS proceed to the next step after a fee payment. If there is evidence of fraudulent behavior the laboratory provides false information or if the laboratory conceals information, BLQS-DMSc shall reject the application.

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

6.2.3 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 laboratory premise as pre-assessment. BLQS-DMSc will inform the name of assessors and the date of pre-assessment before conduct the assessment.

6.2.4 During pre-assessment or initial assessment, if there is evidence of fraudulent behavior, if the laboratory provides false information or if the laboratory conceals information, BLQS-DMSc shall terminate the assessment process.

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

6.2.6 Informs the name of the assessors and appoint the date of the on-site assessment after the applicant laboratory submits the corrective action form of the pre-assessment. In case that applicant laboratory does not request for pre-assessment the processes are omitted. BLQS-DMSc 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.

6.2.7 The laboratory shall correct all nonconformities in the timescale of the requirements for accreditation process of the BLQS-DMSc. The duration for corrective action begins on the date of closing meeting for the assessment. The table of findings (F 07 15 038), corrective actions and supportive evidences, both in the electronic file and the current copy are to be sent to BLQS-DMSC. The timescale of corrective action for the nonconformities forms the various assessments are mentioned as following:

6.2.7.1 For pre-assessment (optional for new accreditation), the laboratory shall submit the corrective action within 30 days. In case that the laboratory cannot complete the corrective action within 30 days, the laboratory can request for extending the duration of corrective action for another 30 days to the Director the BLQS-DMSc, in written, with the reason and the approximate date for completion of all corrective action of nonconformities. After that date, BLQS-DMSc shall immediately conduct the on-site assessment.

6.2.7.2 For on-site assessment of the initial of accreditation, the corrective action for nonconformities shall be carried out within 90 days. In case the laboratory cannot complete the corrective action within 90 days, that laboratory can request for extending the duration of corrective action for another 30 days, in written to the Director of BLQS-DMSc, with the reason and the approximate date for completion of corrective action. However, the duration for proposing of all corrective actions of nonconformities shall be done within 120 days from the date of closing meeting for the assessment. The nonconformities of scope of accreditation, which have not been corrected and closed within the timeframe, are withdrawn or rescinded.

6.2.7.3 For surveillance, re-assessment and extended scope of the accreditation, the laboratory shall carry out the corrective actions of nonconformities within 30 days. In case the laboratory cannot

complete the corrective action within 30 days, that laboratory can request for extending the duration of corrective action for another 30 days, in written to the Director of BLQS-DMSc, with the reason and the approximate date for completion of corrective action. If the laboratory cannot complete the corrective action and closed out nonconformities within the timeframe given, it shall be suspended the accreditation. If the nonconformities of scope of accreditation have not been corrected and closed after suspension of accreditation interval, then those scopes are withdrawn or rescinded.

6.2.7.4 In case of the laboratory cannot submit the evidence for corrective action of nonconformities from the assessment according to 6.2.6.2 or 6.2.6.3 within the timeframe given, and not inform in written with the reason to the Director of BLQS-DMSc. The BLQS-DMSc shall withdraw those scopes of accreditation which are not closed-out the nonconformities.

6.3 The accredited laboratory will receive certificates in Thai and English languages The certificate of accreditation signed by the Director of BLQS-DMSc. The accreditation certificate is valid for 4 years from the date of the Laboratory Accreditation Committee grants the approval. The accredited laboratory can verify its expiration date from the certificate and on BLQS-DMSc website (http://blqs.moph.go.th).

6.4 The laboratory must pay a certificate fee of 2,000 baht as follow as:

6.4.1 If the accreditation certificate is lost, the laboratory can file for request a replacement 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.

6.4.2 In case of damaged accreditation certificate, the laboratory 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 BLQS-DMSc.

6.4.3 For editing in details of accreditation after assessment, the laboratory shall submit the official request memorandum to the Director of BLQS-DMSc enclosed with the edited remark of application form, evidence, principal reference, and reasonable description for non-significance changes from previous assessment. In case for editing in details of certificate of accreditation, the accredited laboratory shall pay the certificate fee following as fee schedule determined by BLQS-DMSc.

7. Obligation for the accredited laboratory

7.1 The accredited laboratory shall commit to continually fulfill the quality management system and technical competence of the accreditation set for the areas, scope which accreditation is sought or granted compliance with the international standard and BLQS-DMSc's requirements at all times of accreditation. This included agreement to adapt to change in the BLQS-DMSC's requirements for accreditation.

7.2 Cooperate to enable BLQS to verify the fulfilment of requirements for accreditation.

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

7.4 Provide access to the information of the independence level and impartiality of the laboratory from its related bodies, where applicable.

7.5 Arrange the witnessing of laboratory services as requested.

7.6 Have, where applicable, legally enforceable arrangements with them customers who commit the customers to provide, on request, access to BLQS assessment teams to assess the laboratory's performance when carrying out testing activities at the customer's site.

7.7 Optionally uses BLQS-DMSc accreditation symbol and/or accreditation statements. In both cases, the accredited laboratory shall inform BLQS-DMSc of the intention to use the BLQS-DMSc accreditation symbol and/or accreditation statements.

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

7.9 Shall immediately stop using or shall not claim BLQS-DMSc 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 laboratory shall inform its affected customer of the suspension, reduction or withdrawal of its accreditation and the associated consequence without undelay.

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

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

7.11.1 Legal status or business status and organization chart.

7.11.2 Top management or Laboratory management who decide for the organization management.

7.11.3 Policy and test method according to the scope of accreditation. The laboratory shall provide BLQS-DMSc with copies of the changes.

7.11.4 Personnel, equipment, and environment that have an effect directly to the test results

7.11.5 Approved signatories for the accredited tests or key personnel.

Note: If the laboratory loses its sole approved signatory, the accreditation status of the laboratory will be suspended.

7.11.6 The claim or the use of BLQS-DMSc accreditation symbol.

7.11.7 Others changes that may affecting the competency of the laboratory.

7.12 Pay fees as determined by BLQS-DMSc.

7.13 Shall assist BLQS to provide the facts in the investigation and resolution of any complaints made by third parties or interested parties on the laboratory’s accredited test.

7.14 Collection and storage of all quality documents for at least 5 years, therefore, the documents can be traceable. The documents can be on various media, such as hard copy or digital.

8. Surveillance

☞ 8.1 On-site surveillance shall be carried out at intervals not exceeding two years of the accreditation cycle. The accredited laboratory shall submit the quality documents for surveillance assessment according to application forms No 1, F 07 15 005, at least 7 months before the certificate reaches 2 years of age, and the surveillance assessment should be conducted at least five (5) months before the certificate reaches 2 years of age. Failure to complete the on-site assessment within the designated time frame may result in suspension the accreditation.

8.2 Another surveillance shall be done, if it is the decision-making from the Laboratory Accreditation Committees, or as a result of a complaint, or there is any evidence indicates that the accredited laboratories may not continuously maintain their quality management system in the previous assessment. The accredited laboratory shall submit the quality documents for surveillance assessment according to application forms No. 1, F 07 15 005 earlier before 3 months of the decision-making schedule.

9. Reassessment

9.1 If the accredited laboratory intends to reaccredit, the complete application forms with required documents for reassessment shall be submitted at lease 7 months of the expiry date. The expired certificate of accreditation shall be valid until the Laboratory Accreditation Committee approves. The renewal assessment shall be established within 5 months of the expiry date. Failure to meet this condition shall be considered as the laboratory does not intend to reaccredit. The accreditation will end on the expiration date on the certificate.

9.2 The laboratory shall submit the complete document as defined in Appendix 1 and 2 with reassessment application forms to BLQS-DMSc.

9.3 The laboratory shall pay for the accreditation fee as indicated.

9.4 In case reassessment that process is ongoing, as follow as:

9.4.1 If the laboratory has complied with all BLQS policies and conditions, including document submission, assessment, and corrective action for nonconformities within the timeframe, but delays occur within the BLQS scope of responsibility (such as the review of corrective actions by assessor or approval of the grant by Laboratory Accreditation Committee). BLQS shall issue a formal letter of re-assessment status.

- If the certificate is approved before the expiration date, the effective date of the new certificate will remain the original date and be extended for another 4 years.
- If the certificate is approved after the expiration date,cthe effective date shall be the date on which the Laboratory Accreditation Committee grants approval, and it will be extended for another 4 years.

9.4.2 If the laboratory has not complied with all BLQS policies and conditions, including document submit, assessment, and corrective action for nonconformities within the timeframe. The laboratory shall be a temporary suspension and the effective date shall be the date on which the Laboratory Accreditation Committee grants approval, and the expiry date shall be the same expiry date as the previous certificate.

10. Extension scope of accreditation (Extending accreditation)

Accredited laboratory can request an extension of the scope of an accreditation to BLQS-DMSc under the timeframe as follows:

10.1 The accredited laboratory shall apply for an extension scope of accreditation at the same time as reassessment and pay for the accreditation fee as indicated, and the laboratory shall submit the document for the extended scope and reassessment according to clause 9.2. If the laboratory submitted the document for extended scope to be late from the timeframe given for reassessment, the BLQS-DMSc shall appoint the assessors for reassessment only. The extended scope shall be a separate laboratory, and the laboratory shall pay for the accreditation fee as indicated.

10.2 The accredited laboratory may request an extension to its scope of accreditation. The accredited laboratory shall submit all of the application forms No. 1 and No. 3 for ISO/IEC 17025 or No. 4 for ISO 15189 or No. 10 for ISO 15190 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 laboratory 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. However, the extensions of scope are not considered if a request is made at a time when the undergoing of surveillance, renewal, or extension of the accreditation process will not be completed.

10.3 In case of the laboratory, an extension scope shall be assessed for at the same time as reassessment according to clause 9.4.

11. Withdrawal / Suspension of the accreditation

11.1 Suspension of accreditation

The Director of BLQS-DMSc will declare a temporary suspension of the accreditation as follows:

11.1.1 The laboratory does not follow the policy, requirements, and conditions of the BLQS-DMSc, such as fees were not paid, the corrective action documents were not proposed within a given timeframe, and the assessment documents were not proposed within a given timeframe.

11.1.2 The laboratory cannot close out nonconformities and reaccreditation within a given timeframe. If the laboratory cannot correct and close out nonconformities within a given timeframe again, BLQS-DMSc will consider withdrawing or reducing the scope of the accreditation, accordingly.

11.1.3 In accordance with clause 11.1.1-11.1.2, the laboratory shall be temporary suspension for 3 months. If the laboratory cannot lift the temporary suspension within 3 months, it shall be withdrawal or reducing accreditation.

11.2 Withdrawal of accreditation

The committee will withdraw the accreditation under the following circumstances.

11.2.1 The laboratory has become bankrupt by court order.

11.2.2 Any practice that violated or did not comply with the Act for "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-DMSc's requirements.

11.2.3 If there is evidence of fraudulent behavior, intentional provision of false information, or concealment of information.

11.2.4 The accredited laboratory terminates its business.

11.2.5 The accredited laboratory requested withdrawal.

11.2.6 The certificate has expired, and the laboratory does not intend to reaccredit. The laboratory can appeal for withdrawal within 15 days after receiving the withdrawal official letter.

11.3 Voluntary Withdrawal

The accredited laboratory can request withdrawal from the accreditation program. The laboratory shall inform the termination by officially document to BLQS-DMSc within 3 official days after acting as clause 11.2.1, 11.2.4, or 11.2.5. They shall immediately stop using or shall not claim BLQS-DMSc accreditation symbol or reference to its accredited status for the activities.

12. Confidentiality

12.1 All information provided by any applicants in relation to preliminary enquiries or to an application for accreditation, and all information obtained in the course of, or in connection with, an assessment of an accredited laboratory shall be completely confidential.

12.2 BLQS-DMSc shall not disclose confidential information about a particular accredited laboratory without the written consent of the accredited laboratory, except where the law requires such information to be disclosed without such consent. All personnel, assessor, and committee of BLQS shall be aware of and abide by this requirement for confidentially. They are required and sign the formal undertaking for maintain confidentially and impartially and declaration of conflict of interest.

13. Appeal

13.1 BLQS establishes guidelines for appeals for Laboratory Accreditation, G 07 15 007.

13.2 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.

13.3 The decision of the Appeal Committee shall be processed within a 3-month period.

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

13.5 During the appeal, the accreditation is still valid.

14. The use of an accreditation symbol or a statement to claim accreditation status

14.1 The accredited laboratory shall demonstrate or show the accreditation symbol as defined in "Policy and Conditions for the Use of an Accreditation Symbol or a Statement to Claim Accreditation Status (N 07 15 009).

14.2 Laboratory shall inform the BLQS-DMSc of the details of the use or non-use of symbol. The laboratory shall attach supporting evidence or sample materials demonstrating the intended use, and formally notify the Bureau of Laboratory Standards in writing.

14.3 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-DMSc, Policy may also legal penalties. The accredited laboratory shall be suspended from accreditation for 90 days if it uses the accreditation symbol and/or accreditation statements out of its scope of accreditation, and may be punished according to the law.

15. Miscellaneous

15.1 BLQS-DMSc may amend the Policies, requirements, and conditions for a medical and health laboratory accreditation stated in the document and other accreditation criteria from time to time as it sees fit. BLQS-DMSc will inform any changes of requirements and conditions on BLQS-DMSc website (http://blqs.dmsc.moph.go.th), which shall be corrected or adjusted within the time frame.

15.2 BLQS may investigate any complaint made to BLQS by third parties against an accredited laboratory concerning activities included in its scope of accreditation. The laboratory shall provide information to BLQS upon

request and shall cooperate with BLQS for the purpose of investigating the complaints.

15.3 BLQS reserves the right not to disclose any complainant.

15.4 The BLQS-DMSc shall not take any responsibility if the laboratory does not conform to the policy, requirements, and conditions of the BLQS-DMSc.

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

15.6 The accredited or suspended, or withdrawn laboratory names, tests, and Methods and accreditation number will be announced in the website (http://blqs.dmsc.moph.go.th).

15.7 The interested party shall submit the application to BLQS-DMSc, within the Ministry of Public Health, Nonthaburi.

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

16.1 Laboratory Accreditation Committee for Medical Laboratory

The responsibilities of this committee are as follows:

16.1.1 To approve the grant of medical laboratories accreditation complying with ISO 15189, ISO 15190, and the policy, requirements and conditions of laboratory accreditation.

16.1.2 To consider and suggestion for suspension, withdrawal, and reducing scope.

16.1.3 To consider and establish for improving the policy, requirement and condition for a medical and health laboratory accreditation.

16.1.4 To delegate other missions.

16.2 Laboratory Accreditation Committee for Public Health Laboratory

The responsibilities of this committee are as follows:

16.2.1 To approve the grant of public health laboratories accreditation complying with ISO/IEC 17025 and policy, requirements, and conditions of laboratory accreditation.

16.2.2 To consider and suggestion for suspension, withdrawal, and reducing scope.

16.2.3 To consider and establish for improving the policy, requirement and condition for a medical and health laboratory accreditation.

16.2.4 To delegate other missions.

16.3 Assessment Report Reviewer for Medical Laboratory Accreditation.

The responsibilities of the reviewer are as follows:

16.3.1 To review the assessment report or the medical testing laboratories complying with ISO 15189, ISO 15190, and the policy, requirements, and conditions for the accreditation before proposing to the laboratory accreditation committee for public health.

16.3.2 To delegate other missions.

16.4 Assessment Report Reviewer for Public Health Laboratory Accreditation.

The responsibilities of the reviewer are as follows:

16.4.1 To review the assessment report or the health products testing laboratories and the forensic science testing laboratories complying with ISO/IEC 17025 and the policy, requirements, and conditions for the accreditation, before proposing to the laboratory accreditation committee for public health.

16.4.2 To delegate other missions.

17. Supplementary Note

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

17.1.1 Application Form No. 1 [F 07 15 005] A request and specific information for laboratory accreditation.

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

17.1.3 Copy of the certificate of registration as a legal entity with registration purposes, and the authorized personnel's name of a Juristic person.

17.1.4 Copy of the trade registration of the commercial registration.

17.1.5 Power of attorney for the applicant. The evidence of authorizing representative and enclosed with 30 Bath of revenue stamp and copy of ID card.

17.1.6 Copy of identification of the applicant (For foreign laboratory).

17.1.7 Application Form No. 3 [(F 07 15 007/02) (ISO/IEC 17025)] or Application Form No. 4 [(F 07 15 069/01) (ISO 15189)] or Application Form No. 10 [(F 07 15 058/01) (ISO 15190)] - General information of quality management system regarding to the related international standards.

17.1.8 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.

17.2 Appendix 2: Submitted documents for accreditation requirements, but not be limited to:

17.2.1 Quality Manual -QM (if any)

17.2.2 Procedure- SP/SOP/QP

17.2.3 Work Instruction- WI/Test method

17.2.4 Copy of all referenced documents for each requested item of accreditation

17.2.5 Result of method validation/ method verification for the requested scope of accreditation

17.2.6 Result of measurement uncertainty

17.2.7 Result of current proficiency testing/interlaboratory comparison

17.2.8 Result of current internal audit

17.2.9 Result of current management review

17.2.10 Result of risk and opportunities