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

2.2 Assessment Report Reviewer.

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

2.3 Laboratory Accreditation Committee (LAC)

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

2.4 Health products

Health products are relate for 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, 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 result 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 the ISO/IEC 17025 and by three or more laboratories for the accreditation submission according to the ISO 15889.

☞ 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.

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 bath 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 180 days, after the date of submitting the application.

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 stationary and the communication apparatus as necessary

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 In case of any amendments or any changes of the policy, requirements and conditions, BLQS-DMSc will inform on BLQS-DMSc website, the accredited laboratory shall commit to follow such change.

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 22870 or 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.

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.

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 per-assessment before conduct the assessment.

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

6.2.5 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 in the item 6.2.3 and 6.2.4 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.

6.2.6 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 form the various assessments are mentioned as following:-

6.2.6.1 For pre-assessment, 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.

6.2.6.2 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.

6.2.6.3 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 day, 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.

6.2.6.4 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.

6.2.6.5 For combination between re-assessment and extended scope of accreditation, or re-assessment, surveillance and extended scope of accreditation, the laboratory shall carry out the corrective action of nonconformities within 30 days. In case that the laboratory cannot complete the corrective action, the laboratory can extend the duration of corrective action according to 6.2.6.3. However, all of the corrective actions shall be done within 60 days.

6.2.7 BLQS-DMSc issues the certificate of accreditation after the Laboratory Accreditation Committee grants the approval. The certificate of accreditation signed by the Director of BLQS-DMSc.

6.2.8 The certificate of accreditation which is combination between re-assessment and extended scope of accreditation, or re-assessment, surveillance and extended scope of accreditation, the issued date is the date of the Laboratory Accreditation Committee grants the approval. If the laboratory

submitted the application for re-assessment earlier before 180 days of expiry date, the expired certificate of accreditation shall be valid until the Laboratory Accreditation Committee grants the approval.

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

6.4 If the accreditation certificate is lost, the laboratory 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.

6.5 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.

6.6 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, principle 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 fulfill continually 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 time 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 fulfilment of requirements for accreditation.

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

7.4 Provide access to the information of 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 their customers that 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 intension 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 misused any of the BLQS-DMSc accreditation logos/or symbol and/or statements. In the way of incorrect references or misleading or misrepresentation, for example using BLQS-DMSc accreditation symbol for unaccredited test and/or unauthorized approved signatory. In these cases, the accredited laboratory shall be suspended of 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 make a decision 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, 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 after the last day of the initial assessment. The accredited laboratory shall submit the quality documents for surveillance assessment according to application forms No 9, F 07 15 037 earlier before 120 days of surveillance schedule and shall pay for accreditation fee as indicated. A second assessment shall be established within 60 days prior to surveillance schedule. 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 complaint, or there is any evidence indicates that the accredited laboratories may not continuously maintain their quality management system in previous assessment. The accredited laboratory shall submit the quality documents for surveillance assessment according to application forms No. 9, F 07 15 037 earlier before 60 days of on-site surveillance schedule.

9. Reassessment

9.1 If the accredited laboratory intends to reaccredit, the complete application forms with ☞ required documents for reassessment shall be submitted earlier before 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 laboratory does not intend to reaccredit. The accreditation will be ended up as the expiration date on the certificate.

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

9.3 The laboratory shall pay for accreditation fee as indicated.

☞ 9.4 The reassessment shall be taken place at intervals not exceeding 4 years after the last day of the initial assessment.

10. Extension scope of accreditation (Extending accreditation)

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

10.1 The accredited laboratory 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 9.2. If the laboratory 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.

☞ 10.2 In case that accredited laboratory 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 laboratory shall submit all of application forms No. 1, No. 2 and No. 3 for ISO/IEC 17025 or No. 4 for ISO 15189 or No. 8 for ISO 22870 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 manners as in the initial assessment. The laboratory shall pay for accreditation fee as indicated. The expiry date of certificate for extension scope shall be the same expiry date of previous certificate.

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, 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.

11.2 Withdrawal of accreditation

The committee will withdraw the accreditation under the following circumstances.

11.2.1 The laboratory has become bankruptcy 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 conceals information.

11.2.4 The accredited laboratory terminates its business.

11.2.5 The certificate is expired and the laboratory does not intend to reaccredit.

The laboratory shall inform the termination by officially document to BLQS-DMSc within 3 official days after acting as clause 11.2.1, 11.2.2 or 11.2.3. The laboratory can appeal for withdrawal within 15 days after receiving the withdrawal official letter.

11.3 Voluntary Withdrawal

The accredited laboratory can request for withdraw from the accreditation program. The laboratory shall inform the termination by officially document to BLQS-DMSc within 3 official days. They shall immediately stop using or shall not claim BLQS-DMSc accreditation symbol or reference to its accredited status for the activities.

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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 laboratories shall be completely confidential.

12.2 BLQS-DMSc shall not disclose confidential information about a particular accredited laboratory without 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 establish guidelines for appeals for Laboratory Accreditation, G 07 15 007.

13.2 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.

13.3 The decision of the Appeal Committee shall processed within at 3 months 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 detail of the symbol exhibition.

14.3 The symbol shall not be abused, misused, or misleaded in the accreditation. Misuse of those symbols to their accreditation status or in any form of the BLQS-DMSc, Policy may be also legal penalties. The accredited laboratory shall be suspended of accreditation for 90 days if it uses the accreditation symbol and/or accreditation statements out of its scope of accreditation, may be punished according to the law.

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 adjusted within the time frame.

15.2 BLQS may investigate any complaint made to BLQS by the 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/third parties, arising directly or indirectly form 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 withdrawn laboratory names, tests, methods and accreditation number will be announced in the website (http://blqs.dmsc.moph.go.th). The certification format of accreditation as mentioned in Appendix 2.

15.7 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 on the grant of medical laboratories accreditation complying with ISO 15189, ISO 22870, ISO 15190, and policy, requirements and conditions of laboratory accreditation.

16.1.2 To approve on the withdrawal of the laboratory accreditation in case that the laboratory is out of business, has become bankruptcy by court order and any practice that violate or do not comply with the BLQS-DMSc requirements.

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

16.2.2 To approve on the withdrawal of the laboratory accreditation in case that the laboratory is out of business, has become bankruptcy by court order and any practice that violate or do not comply with the BLQS-DMSc requirements.

16.2.3 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 22870, 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. Appendix 1

Submitted documents for accreditation application are as follows:

17.1 Application Form No. 1 [F 07 15 005]- Commitment for application of laboratory accreditation.

17.2 Two sets of location maps of the laboratory and nearby landmark building.

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

17.4 Copy of the trade registration of the commercial registration.

17.5 Power of attorney for the applicant. The evidence of authorizing representative and enclosed with 30 Bath of revenue stamp.

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

17.7 Application Form No. 2 [F 07 15 006] - Specific information for accreditation and related documents.

17.8 Application Form No. 3 [(F 07 15 007) (ISO/IEC 17025)] or Application Form No. 4 [(F 07 15 069) (ISO 15189)] or Application Form No. 8 [(F 07 15 086) (ISO 22870)] or Application Form No. 10 [(F 07 15 058) (ISO 15190)] - General information of quality management system regarding to the related international standards.

17.9 Application form No. 9 [F 07 15 037] - Specific information for surveillance.

17.10 Nomination 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.

18. Appendix 2

18.1 Certification format of accreditation (ISO/IEC 17025)

(Certificate of accreditation)

Bureau of Laboratory Quality Standards

Ministry of Public Health

This is to certify that

the laboratory of

…… Accredited laboratory name ……

…….…….. Address …….

has been accepted as an

accredited laboratory complying with the ISO/IEC 17025: …….Year of edition…….

and the requirements of the Bureau of Laboratory Quality Standards

The laboratory has been accredited for specific tests

listed in the scope within the field of

.....Test sample discipline ……..... **Testing**

...…….Signature……

(…….Name – Surname……..)

Director of Bureau of Laboratory Quality Standards

Date of Accreditation …..Date/Month/Year…..

Valid Until……..Date/Month/Year….. Accreditation No. ……/……

(Attachment of certificate of accreditation)

The laboratory of …….. Accredited laboratory name …… **has been accepted as an accredited laboratory in the field of** …… Test sample discipline …… **Testing for the following scopes.**

No.	Type of sample	Test	Method

Accreditation Number : ……..…/……..

Revision No. …….xx (Number of revision) ……. Date of Accreditation : ……. Date/Month/Year……

Date Issued/Revised ……. Date/Month/Year…… Valid Until : ……. Date/Month/Year……

18.2 Certification format of accreditation (ISO 15189)

(Certificate of accreditation)

Bureau of Laboratory Quality Standards

Ministry of Public Health

This is to certify that the laboratory of

…… Accredited laboratory name ……

……..…….. Address …….

has been accepted as an

accredited laboratory complying with the ISO 15189: …….Year of edition…….

and the requirements of the Bureau of Laboratory Quality Standards

The laboratory has been accredited for specific tests

listed in the scope within the field of

Medical Laboratory

..…….Signature……

(…….Name – Surname……..)

Director of Bureau of Laboratory Quality Standards

Date of Accreditation …..Date/Month/Year…..

Valid Until……....Date/Month/Year….. Accreditation No. ……/……

(Attachment of certificate of accreditation)

The laboratory of ……... Accredited laboratory name …… **has been accepted as an accredited laboratory in the field of medical laboratory for the following scopes.**

No.	Type of sample	Test	Method

Accreditation Number : ……..…/……..

Revision No. …….xx (Number of revision) ……. Date of Accreditation : ……. Date/Month/Year……

Date Issued/Revised ……. Date/Month/Year…… Valid Until : ……. Date/Month/Year……

Revised by	Reviewed by	Approved by
Sitaphaisith E		Patravee Soisangwan
Ms. Sitaphaisith Ekachampaka	Mr.Surasak Muenphon	Ms. Patravee Soisangwan

18.3 Certification format of accreditation (ISO 15189 and ISO 22870)

(Certificate of accreditation)

Bureau of Laboratory Quality Standards

Ministry of Public Health

This is to certify that the laboratory of

…… Accredited laboratory name ……

…….…….. Address …….

has been accepted as an

accredited laboratory complying with the ISO 15189: ….Year of edition…, **ISO 22870:** ….Year of edition…

and the requirements of the Bureau of Laboratory Quality Standards

The laboratory has been accredited for specific tests

listed in the scope within the field of

Medical Laboratory and Point of Care Testing

..…….Signature……

(…….Name – Surname……..)

Director of Bureau of Laboratory Quality Standards

Date of Accreditation …..Date/Month/Year…..

Valid Until……..…..Date/Month/Year….. Accreditation No. ……/……

(Attachment of certificate of accreditation)

The laboratory of ……... Accredited laboratory name …… **has been accepted as an accredited laboratory in the field of medical laboratory and point of care testing for the following scopes.**

No.	Type of sample	Test	Method

Bureau of Laboratory Quality Standards ***Page 1 of 1***

Accreditation Number : ……..…/……..

Revision No. …….xx (Number of revision) ……. Date of Accreditation : ……. Date/Month/Year……

Date Issued/Revised ……. Date/Month/Year…… Valid Until : ……. Date/Month/Year……

18.4 Certification format of accreditation (ISO 15190)

(Certificate of accreditation)

Bureau of Laboratory Quality Standards

Ministry of Public Health

This is to certify that the laboratory of

…… Accredited laboratory name ……

……..…….. Address …….

has been accepted as an

accredited laboratory complying with the ISO 15190: ….Year of edition…

and the requirements of the Bureau of Laboratory Quality Standards

within the field of

Medical Laboratory Safety

..…….Signature……

(…….Name – Surname……..)

Director of Bureau of Laboratory Quality Standards

Date of Accreditation …..Date/Month/Year…..

Valid Until……...Date/Month/Year….. Accreditation No. ……/……

19. History of Change

Revision No.	Documentation Changes	Prepared/ Revised by	Date Issued
00	- New SOP	Mrs.Chomchailai Sinthusarn	-
15 - 16	- Add details on-site surveillance (clause 8.3) - Appendix 2 Certificate of accreditation add Revision No. …….xx (Number of revision) ……. and Date Revised ……. Date/Month/Year……	Ms. Waraporn Piyasirananda	2 September 2015
17	- Edit from Assessment Report Reviewer to Assessment Report Reviewer Committee (clause 2.2) - Edit from Assessment Report Reviewer to Assessment Report Reviewer Committee (clause 15.3 and 15.4) - Appendix 2 Certificate of accreditation add a number in table	Ms. Sitaphaisith Ekachampaka	20 October 2016
18	- Appendix 1 has been added in clause 9.2. - Add document code for Application 1, 2, 3, 4, 9 and 10 (clause 16.1, 16.7, 16.8, 16.9)	Ms. Sitaphaisith Ekachampaka	15 March 2018
19	- Added definition of interlaboratory in Clause 2.9 - Changed timeframe of correction action in Clause 6.2.6.3 and 6.2.6.5. - Changed submit for reassessment and extended scope in clause 6.2.8, 6.3 and 9.1. - Added “the time between consecutive on-site assessments shall not exceed two years” in Clause 6.3.	Ms. Sitaphaisith Ekachampaka	28 November 2018

Revision No.	Documentation Changes	Prepared/ Revised by	Date Issued
	- Added more detail in Obligation for the accredited laboratory (clause 7.2-7.6, 7.9 and 7.13) - Changed the expiry date of certificate for extension in clause 10.2. - Added "if there is evidence of fraudulent behavior, intentional provision of false information or conceals information" to clause 11.2.3. - Added confidentiality requirement in Clause 13. - Added information on investigate complaint and maintain confidential information and impartially in Clause 16.2 and 16.3. - Added liabilities in Clause 16.5. - Edited submitted document in Clause 18.		
20	- Added limitation of liability in Clause 16.5.	Ms. Sitaphaisith Ekachampaka	20 March 2019
21	- Added definition "remote assessment" in Clause 2.10. - Added more detail "it is legally responsible for its laboratory activities" in qualification of the laboratory Clause 3. - Edited from top management to authorized director in Clause 4.1. - Added requirement of on-site assessment is not applicable in Clause 4.7. - Added name of the Policy, Requirements and Conditions of the BLQS-DMSc (N 07 15 003) in Clause 5.2.	Ms. Sitaphaisith Ekachampaka	

Revision No.	Documentation Changes	Prepared/ Revised by	Date Issued
	- Added internal audit and review its management system at least once a year in Clause 5.3. - Changed the expiry date of certificate in Clause 6.3. - Added apply for a duplicate copy of the certificate in case of damaged certificate in clause 6.5 - Changed collection and storage of all document for at least 5 years in clause 7.14. - Added on-site surveillance shall be carried out at intervals not exceeding two years in clause 8.1. - Added " another surveillance shall be done, if it is as a result of complaint" in clause 8.2. - Changed detail and time frame of renewal assessment in clause 9.1. - Changed the reassessment shall be taken place not exceeding 4 years after the last day of the initial assessment in clause 9.4. - Removed such special application will cost 2 times more from the normal rate in Clause 10.1, 10.2. - Changed extending accreditation at any time in clause 10.2. - Added Voluntary Withdrawal in Clause 11.3. - Added guideline for appealing, G 07 15 007 in clause 13. - Removed the annual fee in clause 16.8.		

Controlled copy list

1. Director of Bureau of Laboratory Quality Standards	Code No. 07 00
2. Head Laboratory Accreditation Section 1	Code No. 07 03
3. Head Laboratory Accreditation Section 2	Code No. 07 04
4. Quality Manager of Laboratory Accreditation	Code No. QM 07
5. Ms. Sitaphaisith Ekachampaka	