Guideline for the Combination of Surveillance, Reassessment and Extended Scope of Accreditation

1. Purpose

This guideline covers essential accreditation information for an accredited CAB (Conformity Assessment Body, and for a designated staff of the Bureau of Laboratory Quality Standards (BLQS), Department of Medical Sciences (DMSc). Ministry of Public Health (MOPH). The information is about BLQS-DMSc activities for a combination of accreditation certificates in compliance with ISO/IEC 17025, ISO 15189, ISO 22870, ISO Guide 34 and the BLQS-DMSc policies, requirements and conditions, plus with Thai National Standards Act.

2. Application

This document provides the criteria for the BLQS-DMSc accreditation process for surveillance, reassessment and extended scope of accreditation according to ISO/IEC 17025, ISO 15189, ISO 22870, ISO 15190, ISO Guide 34 and the BLQS-DMSc policies, requirements and conditions, plus with Thai National Standards Act.

3. References

3.1 ISO/IEC 17011: 2004. Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

☞ 3.2 APLAC MR – 001: 2014. Procedures for establishing and maintaining the APLAC mutual recognition arrangement amongst accreditation bodies.

3.3 ILAC G – 3: 2012 Guidelines for training courses for assessors used by accreditation bodies.

3.4 National Standards Act, B.E. 2551 (2008). Published in The Royal Government Gazette. Volume 125, Part 42 A, Published Date 4th March A.D. 2008.

3.5 ISO/IEC 17025: 2005. General requirements for the competence of testing and calibration laboratories.

3.6 ISO 15189: 2012 Medical laboratories – Particular requirements for quality and competence.

3.7 ISO 22870: 2006. Point-of-care testing (POCT) – Requirements for quality and competence.

3.8 ISO 15190: 2003. Medical laboratories – Requirements for safety.

3.9 ISO Guide 34: 2009. General requirements for the competence of reference material procedures.

4. Definition and abbreviation

4.1 Accreditation

An accreditation is a procedure which its authoritative body; the BLQS-DMSc; gives a formal recognition to a CAB that is adequately competent to carry out the specific conformity assessment activities. It verifies procedures and results that are technically valid, the CAB signatory person is competent, and the CAB conforms to a quality management system (QMS). IT manifests confidence of the test results, which leads to a public or industry acceptance, a purchaser or regulatory specification, and a national and international recognition. The accreditation ensures a better support in a legal challenge and saves money from a repetitive test. The local accreditation can attain to the international recognition through the Mutual Recognition Arrangement (MRA). Therefore, the work of the accredited CAB is recognized globally, what we aspire to achieve 'Accredited Once Accepted Everywhere'. Even though it confirms conformity of the quality management system, it does not indicate technical credibility of the test results.

4.2 CAB accreditation

A CAB accreditation is a formal recognized system, which aims to develop a good quality management system and a technical competence for the specific type of a laboratory or the specific type of reference material of a reference material producer (RMP). Both of laboratory and producer are called as a CAB. It means regular competency update which will increase confidence in a competency of the CAB. This will induce efficient health care system and save budget of the CAB. The accreditation will endure the system, and continuously improve processes of testing as it will be assessed or by other means.

4.3 Scope of accreditation

The scope of accreditation is a specific conformity assessment activity which is sought or has been granted the accreditation by the Laboratory Accreditation Committees (LAC) of the BLQS-DMSc, MOPH. The BLQS-DMSc is responsible for the laboratory/RMP accreditation of the health products testing, the forensic science testing providing forensic services for the forensic analysis and examination of the forensic scientific evidence as it relates to legal proceeding or for use in court, the clinical sciences and veterinary diagnostic testing and the medical testing. The accredited capability of a CAB is listed in a scope of accreditation. Notably, this scope may not cover all of the activities that the CAB undertakes.

4.4 Accredited CAB

An accredited CAB refers to a laboratory/RMP which has been accredited to some or all of its activities by the LAC of BLQS-DMSc, MOPH. Additionally, the accredited CAB shall continuously conform to the BLQS-DMSc accreditation criteria and requirements. The accreditation would increase confidence level in the accredited CAB activities. This information is only specified in the conformity assessment activities of accreditation which is granted by the LAC of BLQS-DMSc, MOPH. The accredited CAB usually issues a test report/reference material certificate, bearing the combination of BLQS-DMSc accreditation symbol and ILAC-MRA Mark (according to N 07 15 009), as an indication of its accredited status. This mark provides international recognition to a technical competence, a benchmark of performance and a range of marketing advantages. The report/certificate accompanied to export goods will get more acceptances in the oversea markets. This will reduce or eliminate chances of products to be retested in other counties using this International Standards. The combined BLQS-DMSc accreditation symbol and ILAC-MRA Mark demonstrates that the accredited CAB is accredited by a signatory of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

4.5 Approved signatory

An approved signatory means an individual who has been recognized under the BLQS-DMSc accreditation, to sing on the endorses test report/reference material certificate, with the accredited scope of test item(s)/reference material(s). This report/certificate shall be issued by the accredited CAB for the specific activity which is accredited. The accredited CAB shall officially inform the BLQS-DMSc of any changes to its approved signatories. If an accredited CAB loses all its approved signatories for more than three months, its relevant accreditation will be suspended.

4.5.1 Qualification of the approved signatory.

4.5.1.1 He is a staff of, or under contracted with an accredited CAB and who has been authorized by the accredited CAB to sing on the report/certificate.

4.5.1.2 He shall at least graduate the bachelor degree in the Sciences or in a relevant subject which appropriates to the accredited scope. If the approved signatory applies for signing on the specific report/certificate, he should graduate in its specific area. For example, the endorsed pharmaceuticals report/certificate of a government sector should be approved for signing by the approved signatory who at least graduates the bachelor degree in Pharmaceuticals Sciences. For medical laboratories of a government sector, which are accredited in compliance with ISO 15189, ISO 22870 or ISO 15190; their approved signatories shall at least graduate the diploma in the Sciences or

in a relevant subject which appropriates to the accredited scope. For the specific test/reference material area, if there needs any legal personal authorization, an individual shall show a professional authorization certification.

4.5.1.3 He may graduate in equivalent qualifications of clause 4.5.1.2 but the comparability will be assessed on an individual basis ; or at least three years of working experience in the testing laboratory or RMP after obtaining relevant professional qualifications.

4.5.1.4 He shall be qualified to test on the specific test activity.

4.5.1.5 He shall take an oral or writing examination by assessors or the BLQS-DMSc designated staff for appropriate competency monitoring. He shall pass every clause of examination. He shall pass an evaluation on a specific skill competence from his organization. The evaluation will cover all requirements of the technical competence plus knowledge or understanding in an area that he will be investigated.

4.5.1.6 He shall be proposed by the accredited CAB. The accredited CAB shall submit the official letter with supporting evidences for proposing a new approved signatory. For instance of the supporting evidences for showing competencies, are a record of job description, education, technical and quality system training, skill training working experience, probation evaluation, samples of Thai or English signature, *etc.*

4.5.1.7 He, who is responsible for giving an opinion or an interpretation the specific test or reference material or equipment, shall prove his in-depth knowledge of the relevant technical discipline and sub-discipline. He shall pass the appropriate analysis of a blind proficiency sample (where available) and other demonstration of method proficiency and assessment of competence.

4.5.1.8 The new approved signatory shall have been approved from the BLQS-DMSc before signing on the endorsed report/certificate with the BLQS-DMSc accreditation symbol or the combination of BLQS-DMSc accreditation symbol and ILAC-MRA Mark.

4.6 Assessment

An assessment scope of accreditation represents the core of accreditation process. The assessment is a set of operations carried out by the assessment team on behalf of the BLQS-DMSc in order to ensure adequate degree of confidence of the quality management system (QMS) and competence of the entire operations. of a CAB. The assessment activities are generally performed on the premises of the CAB operations. The CAB has to prove its capability to provide reliable services within the defined scope of accreditation, based on the particular standard(s) or guideline(s) or other normative document(s). The assessment operations can be grouped into two practical elements which are the assessment of quality management system (QMS) and the assessment of technical competence. Assessing the technical competence of a CAB is also including the competence of personnel, the validity of

conformity assessment metrology and results. Each of the practical elements of an assessment is chosen to perform a vertical or horizontal assessment. The vertical assessment is a comprehensive assessment to all aspects of each test activity, whereas the horizontal assessment is focused on the one particular aspect through the whole range of activities of the CAB. If a scope of the CAB covers the variety of specific conformity assessment activities, one witness of each test/RMP's task sub-discipline or each test/RMP's task method will be appropriately performed as a representative of the competence. The selected test/RMP's task sub-discipline must be sufficient to draw reliable conclusions for each test/RMP's task sub-discipline or each test/RMP's task method, and it is a reasonable representative sample of the scope of accreditation.

4.7 Type of assessment

There are different types of assessment depending on a status of CAB *i.e.* pre-assessment, on-site assessment for initial or extended scope of accreditation, surveillance on-site assessment, reassessment, follow-up assessment and any extraordinary assessment. Objectives of the extraordinary assessments are to ensure that accredited CAB still conforms to the accreditation requirements, in response to significant changes, customers or other parties' complaints or other matters that may affect the ability of the accredited CAB. The extraordinary assessment is under the BLQS-DMSc consideration, which those changes should be observed at the operation site and reviewed document. The duration for each assessment is varied due to the status and the assessment scope of scope of CAB.

4.8 Condition

A condition (c) is a "very serious indeed" or "quite significant" nonconformity (NC) according to ILAC – G3 Appendix A and ILAC-G20, which non-fulfillment or a deliberate violation by a CAB in relevant to the international standards and the BLQS-DMSc policies, requirements and conditions. The "very serious indeed" nonconformity seriously affects to the accredited CAB activities, it could lead to immediate temporary suspension of the entire scope of accreditation or the affected scope of accreditation. The "quite significant" nonconformity would require proof of implementation of corrective action within a specified time interval. The condition, both type of nonconformity, shall be done by means of identifying clause of criteria and requirement. The nonconformity is an adverse effect to the validity of the CAB activities in both of the QMS and the technical competence. The condition would also mean the observation which was found in the earlier assessment. The condition shall be well responded to the BLQs-DMSc by corrective and preventive actions. The CAB shall resolve an identified nonconformities and describe the specific actions taken for corrective and preventive actions in the specific form (F 07 15 038). Details of each action and all supporting evidences for those actions are required within the specified time interval counting

from the day that an assessment is done. On occasions, the condition could be raised up or changed to the observation, which is under the BLQS-DMSc or the LAC consideration.

4.9 Observation

An observation (O) is a nonconformity, which is minor or isolated and does not affect test results/RMP's tasks. There is not found an evidence of adverse effect on the QMS and technical competence of the CAB activity that is resulted from this type of nonconformity. If there is no action taken on the observation was found, it may be developed into the condition through identifying clause of standard, criteria and requirement. The observation may be treated as recommendations or reminders for reviewing in the next assessment. The observation shall be responded by corrective actions or plan of actions. The CAB shall describe the specific actions taken, to resolve any identified nonconformity in the specific form (F 07 15 038). The detail and supporting evidence of each action or each plan of action shall be provided to the BLQS-DMSc within the specified time interval counting from the day that an assessment is done. A responsive action to the observation will be reviewed in the next assessment. In addition, if the previous observation has not been correct, it will become a condition in the next assessment. On occasions, the observation could be raised up or changed to the condition, which is under the BLQS-DMSc or the LAC consideration.

4.10 Corrective action

A corrective action is an action to eliminate the cause(s) of the detected nonconformity or other undesirable situations. The CAB shall analyze the situation to find the real root cause(s). Then it shall be considered and performed corrective action(s) to eliminate it. The corrective action shall be proven its effectiveness to prevent recurrence of the corrective action requests. If this cause of corrective action request is still remained, it will have a chance to be recurred. Therefore, the completion and effectiveness of the corrective action should be verified. The preventive action plan should be defined, implemented and monitored. Therefore, carrying out and any correction without a proper corrective action, and a recurrence of corrective action request are and an indicator of an insufficient and ineffective correction action. If the CAB responses appear to be insufficient or ineffective, the additionally evidence of effective implementation of actions taken may be requested, or a follow-up assessment may be carried out to verify sufficient and effective implementation of corrective actions, which is under the BLQS-DMSc or the technical expert-committees of accreditation or the LAC consideration.

5. Associated documents

5.1 R 07 15 001: Policies, requirements and conditions for laboratory accreditation.

5.2 R 07 15 004: Policies, requirements and conditions for reference material producer accreditation.

5.3 N 07 15 001: Acceptance criteria for measuring instruments calibration.

5.4 N 07 15 003: Proficiency testing and interlaboratory comparison.

5.5 N 07 15 007: Policies and requirements on estimation of uncertainty measurement and traceability.

5.6 N 07 15 009: Policy and conditions for the use of an accreditation symbol or a statement to claim accreditation status.

5.7 N 07 15 017: Policies and requirements on surveillance for accreditation.

5.8 G 07 15 015: Work manual for accreditation.

5.9 G 07 15 018: Customer manual for accreditation.

6. Principle

6.1 The CAB accreditation is valid for two years.

6.2 The accredited CAB shall conform to the relevant standards and the BLQS-DMSc accreditation policies, requirements and conditions for attaining and maintaining the accreditation.

6.3 Once the initial accreditation, the accredited CAB could be conducted the first surveillance by on-site assessment or desk work, to ensure its ongoing competent. Any required compliance shall be fulfilled according to the accreditation criteria. Then the reassessment will be performed for reaccreditations which is similar to an initial on-site assessment. These assessments will also assess the verification, completion and effectiveness of the corrective action from the previous assessment.

6.4 The accredited CAB shall inform to the BLQS-DMSc within 15 day if there is any significant changes that might be impacted to its quality system. For example of these changes are changing commercial or ownership or organizational status, using the up-date version of reference method, changing important equipment/resource/subcontractor/production planning/material preparation/property value/premise, extending the limit range of testing available, stopping the accredited activity, changing key personnel or given/family name of key personnel in the quality system e.g. top management, quality manager, technical manager, approved signatory staff.

6.4.1 The accredited CAB shall submit official letter to director of the BLQS-DMSc describing and comparing the changer with supporting evidences. For instance, if changing the limit range of testing available, such as the Limit of Detection (LOD) or the Limit of Quantitation (LOQ), the accredited CAB shall show evidences for proving competence and comparing changes. If changing the top management, the accredited CAB shall send the official letter with Thai and English name and signature, including the supporting evidence such as the appointment document, personnel record with education and experience, quality policy statement, *etc.*

6.5 If during the on-site assessment, it has been discovered significant changes, they shall be recorded. Assessor shall check those changes. Those changes shall not fall to any of the critical changes, which are causing to diminish the accredited CAB capability or quality system, especially the changes which are changed from described earlier in the scope of accreditation. If the critical changes are causing to diminish the accredited CAB capability or quality system, and the CAB cannot correct and implement it within the strict specified time limit. Then, the impact scope of accreditation shall be considered for reducing scope of accreditation. Assessor could give an overall opinion for the CAB performance in F 07 15 048 Form to the BLQS-DMSc.

6.6 If the critical changes are causing significant impact to an accredited activity, the relevant scope of accreditation of an accredited CAB shall be suspended or reduced the scope of accreditation or withdrawn. As in the case of, the accredited test/task item has to stop activity more than three months because the main equipment is out of service; the CAB facilities for testing/material production are closed, *etc*. This suspending or reducing the scope of accreditation or withdrawing could be asked by that accredited CAB, itself. The BLQS-DMSc could postpone an assessment plan until the accredited CAB officially proposes the evidence to show its competence for asking the re-accredited status. If the assessment is not in the time limit of an assessment plan, the extraordinary assessment could be conduct.

6.7 If the critical changes are causing significant impact to all of the accredited activities, the accredited CAB shall be suspended. The CAB shall correct and implement those critical changes within the strict specified time limit. If the CAB cannot correct them, this may cause withdraw the accreditation.

6.8 If an accredited CAB has multiple certificates, and each of certificate is required different type of assessment. All of these types of assessment; for instance, surveillance on-site assessment, desk work surveillance, reassessment, or others; could be combined and assessed at the same period. Thereafter if it performed along with the BLQS-DMSc policy, the multiple certificates could be combined (seeing clause 8 and 9). However, it shall take place at intervals not exceeding two years.

6.9 The on-site assessment for surveillance, reassessment and extended scope of accreditation can be combined, upon consideration by the BLQS-DMSc on an individual basis.

6.10 In case the extended scope of accreditation are supplementary to the accredited test/task areas which have already been accredited by the BLQS-DMSc and these extended scopes of accreditation will be performed the on-site assessment within 6 months after the previous time of assessment, the QMS may not necessary being reassessed, as appropriate.

6.11 If the CAB cannot show their competence or there is any suspicious evidence of its competence, the BLQS-DMSc or the technical expert-committees (TEC) of accreditation or the LAC may consider for reducing the specific scope of accreditation or performing the follow-up or conducting the surveillance on-site assessment.

7. Guidelines of each type of assessment

The guidelines of each type of assessment are as follows:

7.1 Guideline of the surveillance of accredited CAB

7.1.1 The surveillance is used as a method to monitor the quality management system and technical competence of accredited CAB that has been accredited from the BLQS-DMSc. It is to ensure that the accredited CAB is consistently performed against the accreditation criteria and requirement until reassessment is started.

7.1.2 The type of surveillance is depending on the accredited CAB status. There are two types of surveillance which are the on-site assessment and the desk work.

7.1.3 The surveillance on-site assessment should take for one to two days depending to scope of accreditation. However, the shortest possible time of assessment is the most preferred. If the scope of assessment is small and simple, the lead assessor and the technical assessor could be the same one. The assessor will concentrate particularly on the area of activity; where there is a reason to believe that relevant standards have not been maintained, or there is an important point issued from the LAC consideration. Furthermore, the assessors will follow-up on the NC(s) which was identified during previous assessments, and also follow-up on any significant quality system changes. This assessment is focused on the critical quality elements especially on the effective implementation of quality management system and technical competence. Changes in organization and management structure, top management, quality manager, technical manager, scope of activities, technical staff, test and calibration procedures, external quality assessment (EQA) plan and result, equipment, calibration or maintenance plan, environmental conditions, and so on; are also examined.

Note:

(a) Occasionally, if there is any evidence indicates that the accredited CAB may not maintain its QMS, or the critical NC(s) from the last assessment may indicate a problem is its quality system, this assessment can be performed prior to the required timeframe. The surveillance on site assessment could be chosen to perform instead of ordinary desk work surveillance, depending on decision making of the LAC of BLQS-DMSc, MOPH.

7.1.4 The desk work surveillance is conducted by the designated staff or experts. This type of surveillance is a self-assessment of the accredited CAB. The surveillance activity refers to historical records survey of the accredited CAB. For reviewing and ascertaining that the accredited CAB continues to maintain the requirements of the relevant standards and the BLQS-DMSc accreditation policies, requirements, conditions and procedures. The accredited CAB shall sign on the worksheet of self-assessment commitment (WS 07 15 001/14) and submit the official letter with supporting evidences. The supporting evidences are evidences of internal audit activity, management review activity and EQA activity which is proficiency testing (PT) program, inter-laboratory comparison (ILC) or intra-laboratory comparison of each accredited activity (referred to N 07 15 003), including other evidences which are from the BLQS-DMSc (referred to 07 15 017).

7.1.4.1 The desk work surveillance should be done within 12 months after the attestation date of accreditation granted. Occasionally, The LAC could call for the surveillance on-site assessment instead of ordinary desk work surveillance, and could also call earlier; such as 6 months after the attestation date; as for examining the implementation.

7.2 Guideline of the reassessment of accredited CAB

7.2.1 The accredited CAB is required reassessment once every the date of expiration.

7.2.2 The accredited CAB shall officially apply and submit the document copy and electronic files for renewal of accreditation for 120 days prior to the expiry date of accreditation. This is allowed the BLQS-DMSc to organize an assessment of the accredited CAB. Therefore, the continuity of the accreditation status is having enough time to arrange and maintain.

7.2.3 The reassessment is closely to a comprehensive re-examination of the CAB's QMS implementation and technical competence to perform specific activities as the initial accreditation. In addition, the effectiveness of the QMS will be assessment in the same format and detail of the detail of the initial assessment.

7.2.4 The reassessment shall be assessed the coherence of accredited CAB compliance with all the accreditation criteria and requirements.

7.2.5 The reassessment usually takes place before the expiry date of accreditation.

7.2.6 If the scope of the CAB covers a variety of specific conformity assessment activities, one witness of each accredited test/task area or each accredited method will appropriately be performed as a representative of the competence. The selected test/task method must be sufficient to draw reliable conclusions for each accredited test/task area or each accredited method and it is a reasonable representative sample of the scope of accreditation.

7.3 Guideline of the on-site assessment for extended scope of accreditation

7.3.1 The submission of the extended scope of accreditation was allowed only in the same time frame of reassessment.

7.3.2 The accredited CAB shall not be allowed to submit the extended scope of accreditation while the previous assessment of accreditation is not yet approved and granted.

7.3.3 If the accredited CAB really needs to apply it at different timeframe of reassessment period, it shall pay the double charge in every item of the accreditation fee.

7.3.4 Procedures of the on-site assessment for extended scope of accreditation shall be performed in the same manner as initial assessment.

7.3.5 The accredited CAB shall submit the official letter to the director of BLQS-DMSc with the reasonable reasons and necessaries, including with the scope of extension.

7.3.6 The accredited CAB shall not be allowed to submit the extended scope of accreditation before getting the approval official letter from the director of BLQS-DMSc.

7.3.7 The accredited CAB might not be allowed to submit the extra scope of extension after the appointment of assessment team, depending on the BLQS-DMSc consideration.

7.3.8 If the submission of the extended scope was proposed prior to the accredited CAB yearly assessment plan, the assessment for its extended scope could be operated at the same period. This is depended on the BLQS-DMSc consideration.

8. Preparation of documents from the CAB

8.1 The CAB shall submit any document and electronic file with the official letter to the director of BLQS-DMSc every time.

8.2 The letter shall be enclosed with the files in a seet of the hard copies and a set of the electronic files in CD/DVD.

8.3 The set of files shall be included with the table list of document and those details for referring *e.g.* the code number, name issued date, revision number.

8.4 The CD/DVD shall be contained with all of documents were submitted which are in the general kind of file and easily read by a general software program and version; such as MS-word file (*.doc), MS-excel file *.xls), MS-powerpoint file (*.pdf), *.pdf, *.jpg, *etc.*

8.5 Any filled form of BLQS-DMSc shall be in MS-word file (*.doc). Other files could be named in the manner that easily understand and refer to the BLQS-DMSc filled from or CAB table list of document.

8.6 Preparation of documents for assessment

8.6.1 The accredited CAB shall review folders and records to demonstrate its QMS and technical competence compliance with the accreditation policies, requirements and conditions. It shall submit the QMS and technical competence procedures, the related quality documents and the implementation records. For example, there are the manual, standard operating procedures, work instructions, worksheets and form for using scientific instrument.

8.6.2 It shall send all of files with and official letter to the BLQS-DMSc prior to the settle date, at least 120 day (4 months). This time interval would allow for future preparation and additional information by request, if necessary. If the assessment team was appointed and date was settled, the BLQS-DMSc can deny any change of document or applied scope of accreditation or test/task method.

8.6.3 The BLQS-DMSc will count the first date on the date of complete files which BLQS-DMSc receives.

8.6.4 The changes in any of the accredited CAB circumstances which may affect to its conformity status to the accreditation criteria and requirements, shall be officially raised in a formal letter format with supporting appropriate reasons to the director of BLQS-DMSc within 15 days.

8.6.5 The required quality documents and records are at least as follows:

8.6.5.1 the official letter to the director of BLQS-DMSc,

8.6.5.2 the complete filled application forms are as follows:

8.6.5.2.1 For a laboratory; Form 1 (F 07 15 005) and Form 2 (F 07 15 006) are submitted for the pre-assessment, on-site assessment for initial or extended scope of accreditation or reassessment,

8.6.5.2.2 For a laboratory; Form 3 (F 07 15 007) for ISO/IEC 17025, or Form 4 (F 07 15 010) for ISO 15189: 2007, or Form 4 (F 07 15 069) for ISO 15189: 2012, or Form 8 for ISO 22870, or Form 10 (F 07 15 058) for ISO 15190, are submitted for the pre-assessment, on-site assessment for initial or extended scope of accreditation or reassessment,

8.6.5.2.3 For a laboratory; Form 9 (F 07 15 037) is submitted for the surveillance on-site assessment,

8.6.5.2.4 For a laboratory; WS 07 15 001/14 and F 07 15 063 are submitted for the ask work surveillance,

8.6.5.2.5 For a RMP; Form 11 (F 07 15 060), Form 12 (F 07 15 061) and Form 13 (F 07 15 062) are submitted for the pre-assessment, on-site assessment for initial or extended scope of accreditation or reassessment,

8.6.5.3 the quality management system and technical competence procedures, work instructions, worksheets, forms and the related quality documents, and the implementation records comply with the relevant standards and the BLQS-DMSc specific criteria and requirement, (The quality documents are involved in test methods, instruments, equipments, internal quality control, facility environment, subcontractor, production planning, material preparation, homogeneity/stability testing, property value assignment, material handling/storage/distribution, *etc.)*

8.6.5.4 the plan, result and summary report of the current internal audit, external audit, management review and preventive action,

8.6.5.5 the plan, result and summary report of proficiency testing (PT) program, inter-laboratory comparison (ILC) or intra-laboratory comparison of each test with satisfied result or report of activities to determine the real root cause and remedial corrective action of unsatisfied result (referred to N 07 15 003),

8.6.5.6 the plan, result and report of measured instruments calibration and maintenance and in-house calibration equipment procedure (referred to N 07 15 001),

8.6.5.7 the plan and summary report of method validation, method verification and estimation of measurement of uncertainty (referred to N 07 15 007),

8.6.5.8 the reference of each scope of test method

8.6.5.9 the master list of quality documents

8.6.5.10 a copy of each accredited (or not accredited for initial assessment) test report or reference material certificate (referred to N 07 15 009)

8.6.5.11 a last year workload or each accredited activity, and

8.6.5.12 any information changes from its accreditation.

8.7 Preparation of documents for corrective action

8.7.1 All required quality documents and records are included at least the following:

8.7.1.1 the official letter to the director of BLQS-DMSc,

8.7.1.2 the completely filled form of corrective action (F 07 15 038),

8.7.1.3 the supporting evidence in hard copy for each of assessor which is classified by each of an identical NC (If there is any supporting evidence which are used for different NC items of different assessors, these hard copy of evidence shall be copied for each of assessor.), and

8.7.1.4 the electronic files of 7.5.1.1 to 7.5.1.3 in a CD/DVD which are clearly arranged and identically named in separate folder of each corrective action. In particular, the F 07 15 038 form shall be in MS-word file (*.doc).

9. Combination of assessments

9.1 Assessment

9.1.1 If any accredited CAB has multiple accreditation certificates and its status requires surveillance or reassessment, or it submits the extended scope of accreditation together with surveillance or reassessment. The scope of each type of assessment can be conducted the assessment at the same period. It is depending on timeframe of its status.

9.1.2 For managing this assessment activity, the initial surveillance on-site assessment can be conducted within 3 months prior or after 12 months of accreditation date; if the CAB status was requested for surveillance on-site assessment.

9.1.3 The extended scope of accreditation during surveillance on-site assessment or reassessment plan will compute from its scope, size, discipline (field area) and per workload of the assessment team that is required to complete the assessment. Number of technical assessors should be adequate to the number of technical expertise to assess in every activity. If the scope of assessment is specific issue, such as using many kinds of equipments or many in-house calibrations, the specific technical assessor for equipment could be appointed. Another instance of a specific technical assessor is a computerized technical assessor for assessing the software program using in the CAB quality system, such as a laboratory Information Management System (LIMS).

9.1.4 The on-site assessment date cold be arranged more than one interval. If assessors of the assessment team are not available at the same period, they could assess in different day. However, the possible single time interval of assessment is the most preferred.

9.1.5 Duration of the technical assessment is depending on its scopes of each assessment.

9.1.6 The QMS should be assessed once and for all of those activities. Furthermore, if the CAB has multiple standards of accreditation certificates which are needed to be assessed at the same period the QMS should be assessed by only one lead assessor who has adequate competency to those standards.

9.1.7 If accredited CAB has multiple accreditation certificates but the surveillance on-site assessment or reassessment is at different period, the QMS may not necessary being reassessed within 6 months after the previous time of QMS assessment as appropriate.

9.1.8 For instance, the available combination of assessments are

9.1.8.1 on-site assessment for surveillance and follow-up,

9.1.8.2 on-site assessment for surveillance and reassessment,

9.1.8.3 on-site assessment for surveillance and extended scope of accreditation,

9.1.8.4 on-site assessment for reassessment and extended scope of accreditation, or

9.1.7.5 on-site assessment for surveillance, reassessment and extended scope of accreditation.

9.2 Corrective action and summary report of assessment

9.2.1 A written report on the outcome of the assessment shall be promptly brought to the attention of the CAB. After assessment, the CAB shall response and describe the specific action taken to the corrective action requests in F 07 15 038 form with supporting evidence or plan of action within 15 days (1/2 month) for follow-up, 30 days (1 month) for surveillance on-site assessment and reassessment and 90 days (3 months) for extended scopes of accreditation.

9.2.2 The requests of corrective action to the QMS shall be fully addressed within the shortest required duration of the assessment type in its combination schedule of assessment. The requests of corrective action to the technical assessment of each scope shall be fully addressed within the required duration of each assessment type. The corrective actions of QMS assessment are involved in every scope of assessment.

9.2.3 If the accredited CAB cannot fully address to the corrective actions within the assessment required duration, it can raise a postponed official letter to extend the period of time. However, the requested date for extending period is not more than 30 days from prior required date. Normally, all conditions and observations shall be corrected and reported to BLQS-DMSc within 120 days (4 months). After closing conditions and observations, the designated staff of BLQS-DMSc may request for additional evidence of effective and sufficient implementation of corrective actions taken or any supporting information for accreditation. Each of nonconformity could be grouped or reduced or added up or changed type from condition

to observation or observation to condition, which are depending on the consideration of the BLQS-DMSc, the technical expert-committees (TEC) of accreditation, and the LAC. This changing is informed to assessors and CAB by using the F 07 15 049 form.

9.2.4 If it is a combination of assessments and all conditions/observations were closed within the specific timeframe, the summary report of every type of assessments will be together prepared and proposed to the technical expert-committees (TEC) of accreditation for consideration. Then the approved summary report shall be prepared and proposed to the LAC for accreditation granted. The technical expert-committees (TEC) of accreditation or the LAC may request for additional evidence of effective and sufficient implementation of corrective actions taken or any supporting information for accreditation.

9.2.5 If it is only surveillance; either on-site assessment or self-assessment (self-declaration); the summary report shall be presented to the director of BLQS-DMSc for approval. The report for surveillance on-site assessment is presented as the same format for the LAC, except descriptive table or paragraphs of each clause of relevant standards. This report for self-assessment (self-declaration) is presented the summary of scope of accreditation, proficiency testing (PT) program inter-laboratory comparison (ILC), intra-laboratory comparison, internal audit, management review, and significant quality system changes.

9.2.6 The reducing scope of accreditation (scope trimming) or the follow-up assessment or the surveillance on-site assessment could be raised by the technical expert-committees (TEC) of accreditation or the LAC consideration.

9.2.7 If the corrective action for nonconformities of any scope of reaccreditation, surveillance or extended scope of accreditation could with specific timeframe, this scope shall be cut of from the scope which is proposed to TEC and LAC for accreditation grant.

10. Combination of certificates of the accreditation

10.1 The accredited CAB shall make all payments before the certificate is issued. If the certificate is issued before all payments were paid, the accredited CAB should be suspended.

10.2 The accredited CAB shall return the previous certificates which are already combined in the new combination certificate after receiving the new one.

10.3 The accredited CAB has no rights no rights to apply or submit any document for any assessment until all payments were paid and the last accreditation process is done.

10.4 Requirements for the combination of certificates of accreditation

10.4.1 An accreditation scope is the supplementary to the test/task area which are already accredited according to ISO/IEC 17025, ISO 15189, ISO 22870, ISO 15190 or ISO Guide 34 by the BLQS-DMSc accreditation given.

10.4.2 The accreditation scope can be combined in to one certificate of accreditation if the accredited CAB was performed as follows:

10.4.2.1 was on-site assessed, and

10.4.2.2 was required a new certificate to be issued.

10.5 Accreditation date of the new combination of certificates of accreditation

10.5.1 The accreditation date of the new combination of certificate shall be issued as the following.

10.5.1.1 If there are combined with the extended scope of accreditation, the available date of accreditation certificate date shall be on the date of a new accreditation of the extended scope of accreditation which is granted by the LAC. Nonetheless, the new combination certificates of accreditation can be extended maximum to 2 years from the expiry date of previous certificate of accreditation.

10.5.1.2If there are not combined with the extended scope of accreditation, the available date of accreditation shall be on the date of reaccreditations which is continued to the previous expiry date.

10.6 Extra requirement of combination of reaccreditation certificates

10.6.1 If the accredited CAB has already applied and submitted for renewal of accreditation and the reassessment procedure id in process, the validity of accreditation certificate can be extended to 3 months after the expiry date. If the reaccreditations process was performed in the combination schedule with the extended scope of accreditation, the validity of accreditation certificate can be extended to 7 months after the expiry date.

10.6.2 Every process for re-granting and issuing the reaccreditations certificate should be completely performed within 3 months after the previous expiry date. In this case, if the on-site assessment for surveillance or extended scope of accreditation process is taken in time of the reaccreditations certificate requirement, its scope could be included in this new certificate of reaccreditations.

11. History of change

Revision No.	Documentation Changes	Prepared / Revised by	Date Issued
00	New SOP	Ms. Waraporn Piyasirananda	-
01-05	- Edit the reference to current in clause 3.2 and 3.8 - Add ILAC-G3 Appendix A and ILAC-G20 in clause 4.8 - Add details The CAB accreditation is valid for two years in clause 5.1 - Add details Note: (a) in clause 6.1.3 - Add details Surveillance in clause 6.1.4.1 - Edit form for a laboratory in clause 7.6.5.2.2 - Add wording surveillance on-site assessment in clause 8.1.2	Ms. Waraporn Piyasirananda	26 August 2014
06	- Edit the reference to current in clause 3.2 - Take-out clause 3.4 ILAC G-10 and 3.5 ILAC G-20	Ms. Sitaphaisith Ekachampaka	

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. QCC 07
5. Ms. Sitaphaisith Ekachampaka