Policy and requirements for proficiency testing, interlaboratory comparison/ laboratory's performance assessment in test

1. Purpose

This policy and requirements of the BLQS-DMSc aim to use the activities of proficiency testing (PT), interlaboratory comparison (ILC) and laboratory's performance assessment in test, as a tool of the accreditation process for testing laboratory, reference material producer (RMP), and biobanking accreditation.

2. Application

Scope of this policy and requirements are as follows:

2.1 Participation in proficiency testing and interlaboratory comparison of testing laboratories, reference material producer, and biobank that apply for accreditation, and have already been accredited.

2.2 The consideration for PT result and interlaboratory comparison comply with the ISO/IEC 17043 or the national recognized standards.

3. References

3.1 ISO/IEC 17011: 2017. Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

3.2 ILAC P9:01/ 2024. ILAC Policy for proficiency testing and/or interlaboratory comparisons other than proficiency testing.

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

3.4 ISO 15189: 2022. Medical laboratories-Requirements for quality and competence.

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

3.6 ISO 15190: 2020. Medical laboratories-Requirements for safety.

3.7 ISO 20387: 2018: Biotechnology-Biobanking-Gerneral requirements for biobanking.

3.8 ISO/IEC 17043: 2023. Conformity assessment-General requirements for the competence of proficiency testing providers.

3.9 ISO 13528: 2022 Statistical methods for use in proficiency testing by interlaboratory comparisons.

3.10 EA-4/18G : 2021. Guidance on the level and frequency of proficiency testing participation.

4. Definition and Abbreviation

4.1 Proficiency testing (PT) is the evaluation of participant performance against pre-established criteria using interlaboratory comparisons. (refer to ISO/IEC 17043 Conformity assessment-General requirements for the competence of proficiency testing providers) that ISO 15189:2022 uses external quality assessment also known as proficiency testing.

☞ 4.2 Interlaboratory comparison (ILCs) is the organization, performance and evaluation of measurements or tests under the predetermined conditions on the same or similar items by two laboratories for the accreditation submission according to ISO/IEC 17025, ISO 17034, and ISO 20387, and by three laboratories for the accreditation submission according to ISO 15189 in conjunction with your own results.

4.3 Laboratory's performance assessment in test is one of the tools used to evaluate the laboratory's performance using intercomparison of test results between analysts or using other mechanisms for evaluation of the laboratory's performance.

4.4 Conformity Assessment Bodies, CABs: testing laboratory, reference material producer, and biobanking.

5. Associated document

5.1 N 07 15 029 Guidelines for Alternative Assessment Procedures for Medical Laboratories.

6. Procedures

The CABs shall be required to plan and monitor its participation in PT and/or ILCs or Laboratory's performance assessment in test respectively.

Requirements

6.1 In case the PT providers are available.

CABs shall participate in test parameters or measurand or test methods for each discipline that they apply for accreditation. However, CABs shall have a mechanism to ensure that the PT test item is distributed among the various analysts that trained and qualified for the relevant tests. The criteria requirements for the selection of the PT providers for participation are as follows:

6.1.1 Recognition of PT providers according to the ISO/IEC 17043

☞ 6.1.2 Recognition of a government, private, state enterprise, association, or professional organization that has organized a program and summarized the results officially.

6.1.3 The source of PT providers can be searched by accessing the website: www.blqs.dmsc.moph.go.th and the website of PT provider schemes in Appendix 1.

6.1.4 CABs shall establish a plan for participation in PT schemes that covers the scope of their accreditation as mentioned in Appendix 2 and 3. In case CABs participates with the other PT providers which does not in the list of PT Providers as mentioned in Appendix 1, CABs shall officially propose the performed evidence to the BLQS-DMSc and submit the evidence to demonstrate the competency of the PT providers that participated.The BLQS-DMSc shall decide for the competency of those PT providers.

☞ **6.2 In case the PT providers are not available.**

CABs shall carry out the interlaboratory comparisons by two laboratories for the accreditation submission according to ISO/IEC 17025, ISO 17034, and ISO 20387, and by three laboratories for the accreditation submission according to ISO 15189 in conjunction with your own results, and consider taking action according to the following

6.2.1 interlaboratory comparisons with an external agency that acts as a proficiency testing service, providing test materials to members and evaluating them, but is not accredited to ISO/IEC 17043.

6.2.2 interlaboratory comparisons with the same level of competency using an accredited laboratory to comply with ISO/IEC 17025, ISO 15189 or ISO 17034 or ISO 20387 or equivalent standards is College of American Pathologists; CAP. The participating laboratories should have the test item requested for carrying out the interlaboratory comparison in the same technique/the same matrix.

6.2.3 In clause 6.2.1-6.2.2, CABs shall establish the procedure for their performance assessment in tests (as mentioned in Appendix 3). The procedure should adequately describe the preparation or provision of the sample or test item, demonstrate the accurate value of the test item, statistical techniques applied to review or evaluate the results.

6.3 In case the PT providers and interlaboratory comparison are not available.

CABs shall carry out to compare the test results or measurand using the laboratory's performance assessment between analysts of the laboratory. CABs shall establish the procedure for their performance assessment in test or measurand (as mentioned in Appendix 3). The procedure should be adequately described such as sample preparation for performance assessment between analysts, criteria for demonstrating the accurate value of the analyte, statistic technique used for evaluating such as ISO 13528 or the appropriate statistics, plan, and frequency for assessment among the trained analyst, record and report. For ISO 15189 refer to the Guidelines for Alternative Assessment Procedures for Medical Laboratories (N 07 15 029).

6.4 Frequency in participation of proficiency testing schemes / interlaboratory comparison/ laboratory's performance assessment in test.

6.4.1 Frequency in participation of proficiency testing schemes should depend on the rounds of the PT providers or at least once a year or as appropriate. However, CABs shall ensure the evidence of their performance that shall be demonstrated on on-site surveillance and re-assessment.

6.4.2 Frequency in the interlaboratory comparison and the laboratory's performance assessment in test shall be carried out at least once a year or as mentioned in the plan of laboratories. However, CABs shall ensure the evidence of their performance that shall demonstrate on-site surveillance and re-assessment.

6.5 Reporting of proficiency testing / interlaboratory comparison / laboratory's performance assessment in test. CABs shall submit the report of those activities to the BLQS-DMSc before an assessment schedule, please refer detail to application form no.1: A report and specific information for laboratory accreditation (F 07 15 005). In case the data of F 07 15 005 cannot complete, that CABs shall be submitted the table of summary proficiency testing, interlaboratory comparison and laboratory's performance assessment in test (F 07 15 063). **If the result of proficiency testing is unsatisfactory**, CABs shall carry out as follows:

6.5.1 Determine the root cause, remedial corrective action and report to the BLQS-DMSc.

6.5.2 The BLQS-DMSc shall inform the assessor to examine the corrective action of those results.The acceptance criteria for the result of proficiency testing are evaluated by the statistical criteria of the proficiency testing provider or using the statistic Z-score.

$$|Z| \leq 2 \text{ Satisfactory}$$
$$2 < |Z| < 3 \text{ Questionable}$$
$$|Z| \geq 3 \text{ Unsatisfactory}$$

6.5.3 The acceptance criteria for interlaboratory comparison/laboratory's performance assessment in test should depend on the statistics used in the internal quality control of laboratory testing or other statistics that followed ISO 13528 for example T-test, F-test, or other appropriate statistics.

6.5.4 The BLQS-DMSc shall decide for the unsatisfactory performance in the PT scheme according to the ISO/IEC 17043 that CABs shall take corrective actions within agreed timeframes. Accredited scope or requested scope for accreditation that the proficiency testing results found unsatisfactory, without any investigation and corrective action shall be temporary suspension.

6.5.5 The decision of BLQS-DMSc for temporary suspension through withdraw will depend on the decision-making of the Accreditation Committees for testing laboratories, reference material producer (RMP), and biobank accreditation.

7. Data record and Used document

7.1	Appendix 1	:	The source of PT providers
7.2	Appendix 2	:	Accreditation Scope Discipline
7.3	Appendix 3	:	Actions for accredited laboratories and accreditation bodies
7.4	F 07 15 005	:	Application no.1 : A request and specific information for laboratory accreditation

8. Supplementary notes

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9.History of Change

Revision No.	Documentation Changes	Prepared /Revised by	Date Issued
00	Initial Document	Panadda Wiroonboonpat	
11	- Edited the reference to current (No.3.9) - Edited prepared by /controlled copy list - Added website in appendix	Saovanee Aromsook	26 OCT 2016
12	- Edited the reference from ISO G.34 (Section 5.3,5.15) to ISO 17034: 2016 (Section 6.2,7.12)	Saovanee Aromsook	24 OCT 2017
13	- Edited the reference to current - Added detail of ISO/IEC 17043	Saovanee Aromsook	12 DEC 2018
14	- Updated the reference from APLAC MR 001:2017 to APAC MRA-001:2019 (Section 3.2) - Deleted the reference to used the latest valid (Section 3.3) - Updated the PT providers schemes in appendix 1 to current	Saovanee Aromsook	15 OCT 2019
15	- Updated the reference from APAC MRA 001:2019 to APAC MRA-001:2021 (Section 3.2) - Added the reference to use (Section 3.9) - Added the association documents (Section 5) - Edited the control copy list	Saovanee Aromsook	30 AUG 2021

Revision No.	Documentation Changes	Prepared /Revised by	Date Issued
	- Deleted detail no.30 of appendix 1 accordance to ISO/IEC 17025 - Added detail no.10 of appendix 1 accordance to ISO 15189		
16	- Added a biobank unit to the purpose, usability and comparison of test results (Section 1, Section 2, and Section 4.2) - Update reference documents to be current (Section 3) - Deleted reference from APAC MRA 001 (Section 3.2) - Added definitions and abbreviations for External quality assessment (Section 4.1) and CAB (Section 4.4) - Add N 07 15 029 of related document (Section 5.1) - Edited the policy to make it clear that laboratories must participate in PT as a primary criterion and use the term CAB instead of LAB (Section 6) - Added the case of not having a source to participate in testing and comparing test results between laboratories. For ISO 15189, there is N 07 15 029 that can be carried out (Section 6.3) - Added detailthe data cannot complete. (Section 6.5)	Saovanee Aromsook	19 MAR 2024

Revision No.	Documentation Changes	Prepared /Revised by	Date Issued
	- Specify comprehensive of proficiency testing service sources (Appendix 1) - Edited the name of the approver to be current		
17	- Edited clause 4.2 and 6.2 Interlaboratory comparison (ILCs) is the organization, performance and evaluation of measurements or tests under the predetermined conditions on the same or similar items by two or more laboratories for the accreditation submission for according to ISO/IEC 17025 and ISO 15189. - Deleted clause 7 record and used document clause 7.5 The table of summary proficiency testing, interlaboratory comparison and laboratory's performance assessment in test.	Saovanee Aromsook	9 OCT 2025
18	- Edited clause 4.2 and 6.2 Interlaboratory comparison (ILCs) is the organization, performance and evaluation of measurements or tests under the predetermined conditions on the same or similar items by two or more laboratories for the accreditation submission for according to ISO/IEC 17025 and ISO 15189. - Edited clause 6.1.1 identify for selection of the PT provider.	Saovanee Aromsook	OCT 2025

Revision No.	Documentation Changes	Prepared /Revised by	Date Issued
	- Edited clause 6.2 identify for approach of interlaboratory comparison.		

Appendix 1

Website: PT providers schemes

1. ACCREDIA - L'Ente Italiano di Accreditamento, Italy
2. Accreditation Body of Serbia, Serbia
3. American Association for Laboratory Accreditation, United States Of America
4. ANSI National Accreditation Board, United States Of America
5. Association of Analytical Centers 'Analitica', Russian Federation
6. Belarusian State Centre for Accreditation, Belarus
7. Belgian Accreditation Structure, Belgium
8. Bureau of Laboratory Accreditation, Department of Science Service, Ministry of Higher Education, Science, Research and Innovation, Thailand
9. China National Accreditation Service for Conformity Assessment, China
10. Comite Francais D'accreditation, France
11. Coordenacao Geral de Acreditacao, General Coordination For Accreditation, Brazil
12. Czech Accreditation Institute, Czech Republic
13. Danish Accreditation Fund, Denmark
14. Department of Standards Malaysia, Malaysia
15. Deutsche Akkreditierungsstelle Gmbh, Germany
16. Dutch Accreditation Council, Netherlands
17. Egyptian Accreditation Council, Egypt
18. Entidad Mexicana de Acreditacion A.C., Mexico
19. Entidad Nacional de Acreditacion, Spain
20. Federal Service for Accreditation, Russian Federation
21. Finnish Accreditation Service, Finland
22. Georgian Accreditation Center - The Unified National Body of Accreditation, Georgia
23. Hellenic Accreditation System - ESYD, Greece
24. Hong Kong Accreditation Service, Hong Kong, China

25. International Accreditation New Zealand, New Zealand
26. Japan Accreditation Board, Japan
27. Korea Laboratory Accreditation Scheme, Korea
28. National Accreditation Authority, Hungary
29. National Accreditation Board for Testing & Calibration Laboratories, India
30. National Accreditation Body of Indonesia, Indonesia
31. National Association of Testing Authorities, Australia, Australia
32. Norsk akkreditering, Norway
33. Organismo Nacional de Acreditacion de Colombia, Colombia
34. Perry Johnson Laboratory Accreditation, Inc, United States Of America
35. Polish Centre for Accreditation, Poland
36. Romanian Accreditation Association, Romania
37. Singapore Accreditation Council, Singapore
38. Slovak National Accreditation Service, Slovakia
39. South African National Accreditation System, South African
40. Standards Council of Canada, Canada
41. Swedish Board for Accreditation and Conformity Assessment, Sweden
42. Taiwan Accreditation Foundation, Chinese Taipei
43. Turkish Accreditation Agency, Türkiye
44. United Kingdom Accreditation Service, United Kingdom

Appendix 2

Accreditation scope discipline

1. **Biological-General**

   Sub-disciplines Include:

   1. Qualitative Bacteriology
   2. Qualitative Mycology
   3. Qualitative Virology
   4. Molecular sub-typing
   5. Serology
   6. ELISA
   7. PCR
   8. Microscopy
   9. Quantitative Microscopy
   10. Qualitative Microscopy

2. **Chemical-General**

   Sub-disciplines:

   Chromatography

   1. TLC
   2. GC, GC-MS, GC-MS/MS
   3. HPLC, HPLC MS/MS
   4. UPLC, UPLC MS/MS
   5. IC

   Spectroscopy

   1. AAS
   2. GFAAS
   3. Fluorescence
   4. ICP, ICP-OES
   5. IR, FTIR
   6. UV/VIS Spectroscopy Technique

   Titration

   1. Potentiometry

   Gravimetric

   1. Gravimetry

3. Mechanical

Sub-disciplines:

1. Tensile
2. Dimension
3. Bursting pressure and volume
4. Water leakage
5. Oven conditioning
6. Filtration (Minimum HVL for X-ray)
7. Beam-limiting devices (Type of dental radiation for dental radiography using intra-oral image receptors, a beam-limiting devices or cone)
8. Distance of focus from the light source
9. Diameter of a beam-limiting
10. Leakage radiation

Materials/Matrices/Product Types

1. Food:

1. Milk and milk products
2. Egg and egg products
3. Meat and meat products (fresh, frozen, chilled, heat treated, processed)
4. Aquatic animal and aquatic animal products (fresh, frozen, heat treated, processed)
5. Poultry and poultry products (fresh, frozen, heat treated, processed)
6. Vegetable and vegetable products
7. Cereals and grain products
8. Legume and legume products
9. Algae and algae products
10. Fruit and fruit products
11. Flour and flour products
12. Oil, fat and butter
13. Supplementary foods for infant and young children
14. Condiments, sauce and spices
15. Noodle and noodle products
16. Semi-processed food
17. Infant foods
18. Snack food and desserts
19. Ready-to-eat foods
20. Water, ice, bottled drinking water and supply water, potable water
21. Beverage
22. etc.

2. Drug:

1. Tablets
2. Liquid
3. Capsule
4. etc.

3. Cosmetic:

1. Hair cosmetic products: cold-wave, straightening, hair dye, bleaching, hair dressing, anti-dandruff, Shampoo and conditioner
2. Face cosmetic products: anti-acne-anti-melasma cream, anti-melasma cream, sunscreen cream, creams and lotions, lipstick, eye-pencil, eyebrow, eye shadow, toothpaste, dental floss, mouthwash, anti bacterial bacterial spray
3. Body cosmetic products: talcum, body lotion, soap, etc.
4. etc.

4. Household products:

1. Pesticide products
2. Larvicide sand granules products
3. Repellent products
4. Rodenticides, Tick Flea products
5. Cleaning and amend of pipe clogged products
6. Disinfectant products
7. Bleaching clothes
8. Correction fluid products
9. etc.

5. Toxicology:

1. Biological samples, Clear water sac, Water bladder, Organs.
2. etc.

6. Narcotic:

1. Urine
2. Biological sample, Suspected sample
3. Dry plants
4. etc.

7. Medical materials and medical devices:

1. condoms
2. Examination Gloves
3. Syringes
4. X-ray equipments (Diagnostic)
5. etc.

8. Veterinary diagnostic sample / Livestock products testing:

1. Muscle
2. Dog Chew
3. Egg and egg products
4. Animal fat
5. Internal organ, Visceral organ
6. Carcass
7. Animal hide
8. Animal serum
9. Milk and milk products
10. Milk
11. Honey and royal jelly
12. Animal tissue and processed products
13. Meat and meat products
14. Urine
15. Mammal brain

9. Forensic sample:

1. Blood
2. Urine
3. Serum
4. Aqueous humor
5. Other liquid media
6. Non biological / physical evidence

Appendix 3

Actions for accredited laboratories:

1. Appropriate participation in proficiency testing, both in proficiency testing and interlaboratory comparisons, covering the scope of the laboratory's accreditation, in a useful and cost-effective manner. The laboratory should satisfy itself of the competence of the providers of PT schemes in which they voluntarily participate.
2. The laboratory policy for participation in proficiency tests as a form of external quality control should be adequately described in the Quality Manual or in other operational documents of the laboratory. This particularly concerns planning, performance/operation, evaluation, corrective action, records and its storage.
3. The procedure for perform an interlaboratory comparison and laboratory' performance shall documented with details as specified in clause 2.
4. The laboratory should be prepared to justify non-participation in readily available proficiency testing schemes, where one or more appropriate schemes exist.

Actions for accreditation bodies and assessors:

1. Promotion of the benefits of participation in proficiency testing, and how performance is used to help assess the competence of laboratories.
2. Supporting of organization or arrangement of proficiency tests, wherever possible and useful in the most cost-effective manner.
3. The accreditation body should judge the appropriateness of proficiency tests in which the laboratory participates, which will be taken into account in the accreditation. Where the accreditation body recommends participation in any particular PT scheme, for its accredited laboratories, in should satisfy itself of the competence of the organization providing the proficiency test.
4. Ensuring that assessors have the following competences:
    - Have demonstrable competence in interpretation of the assigned value and acceptability criteria in all types of proficiency testing in order to afford a critical evaluation of quantitative and qualitative results of laboratories;
    - Have relevant knowledge about standards and Guidelines on the organization, performance and evaluation of interlaboratory comparisons, e.g. ISO/IEC 17043, ISO 13528.
5. Check that laboratories have a written procedure in the Quality Manual (QM) or in laboratory instructions covering participation in proficiency testing, including how the performance in proficiency testing is used to demonstrate the laboratory's competence and procedures followed in the event of unsatisfactory performance.