

**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 for accreditation in a medical, public health testing laboratory, a forensic science laboratory and a reference material producer (RMP).

2. Application

Scope of this policy and requirements are as follows:

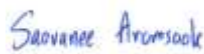
2.1 Participation in proficiency testing and interlaboratory comparison of testing laboratories or RMPs which apply for accreditation, and has already been accredited.

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 APAC MRA-001: 2021. Procedures for establishing and maintaining mutual recognition amongst APAC accreditation bodies.
- 3.3 ILAC P9:06/ 2014. ILAC Policy for participation in proficiency testing activities.
- 3.4 ISO/IEC 17025: 2017. General requirements for the competence of testing and calibration laboratories.
- 3.5 ISO 15189: 2012. Medical laboratories-Requirements for quality and competence. Section 5.6
- 3.6 ISO 17034: 2016: General requirements for the competence of reference material procedures.
- 3.7 ISO/IEC 17043: 2010. Conformity assessment-General requirements for proficiency testing Annex A: Types of proficiency testing schemes. Annex B: Statistical methods for proficiency testing. Annex C: Selection and use of proficiency testing.
- 3.8 ISO 13528: 2015 Statistical methods for use in proficiency testing by interlaboratory comparisons.
- ☞ 3.9 EA-4/18 : 2010. Guidance on the level and frequency of proficiency testing participation.

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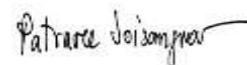
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4. Definition and Abbreviation

4.1 Proficiency testing (PT) is the evaluation of participant performance against pre established criteria by means of interlaboratory comparisons. (refer to ISO/IEC 17043 Conformity assessment-General requirements for proficiency testing)

4.2 Interlaboratory comparison (ILC) is the organization, performance and evaluation of measurements or tests under the predetermined conditions on the same or similar items by two or more laboratories for the accreditation submission according to the ISO/IEC 17025 or ISO 17034, and by three or more laboratories for the accreditation submission according to the ISO 15189.

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

5. Association Documents

☞ 5.1 F 07 15 016 List of proficiency scheme provider & scope of accreditation for medical laboratory that participate in proficiency testing.

☞ 5.2 F 07 15 018 List of proficiency scheme provider & scope of accreditation for health products or public health laboratory that participate in proficiency testing.

6. Procedures

Policy and requirements

6.1 In case that the PT providers are available. The laboratories or reference material producers (RMPs) shall participate in test parameters or measurand or test methods for each discipline that they apply for accreditation. However, the laboratory or reference material producer (RMP) shall have mechanism to ensure that the PT test item shall distribute among the various analysts that trained and qualified for the relevant tests. The criteria requirements for selection the PT providers for participation are as follows:

6.1.1 Shall be the recognition PT providers in the international, national or group of related expert.

6.1.2 Source of PT providers can search by access the website: www.blqs.dmso.moph.go.th and website of PT provider schemes in medical and public health testing laboratories mentioned in Appendix 1.

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6.1.3 Laboratory shall establish plan for participation in PT schemes covers the scope of their accreditation as mentioned in Appendix 2 and 3. In case that the laboratory participate with the other PT providers which does not in the list of PT Providers as mentioned in Appendix 1, the laboratory 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 make a decision for the competency of those PT providers.

6.2 In case that the PT providers are not available. The laboratories shall carry out the interlaboratory comparisons by two or more laboratories for the accreditation submission according to the ISO/IEC 17025 or ISO 17034, and by three or more laboratories for the accreditation submission according to the ISO 15189. The participated laboratories should be the same level of competency by means of an accredited laboratory comply with ISO/IEC 17025 or ISO 15189 in the test item requested for carried out the interlaboratory comparison in the same technique / the same matrix. Laboratories shall establish the procedure for their performance assessment in test (as mentioned in Appendix 3). The procedure should be adequate described the preparation or providing of sample or test item, demonstrate the accurate value of the test item, statistical techniques applied to review or evaluate the results. Source of interlaboratory comparison can search by access the website: www.blqs.dmhc.moph.go.th

6.3 In case that the PT providers and interlaboratory comparison are not available. Laboratories or reference material producers (RMPs) shall carry out to compare the test results or measurand by means of the laboratory's performance assessment between analysts of the laboratory. Laboratories or reference material producers (RMPs) shall establish the procedure for their performance assessment in test or measurand (as mentioned in Appendix 3). The procedure should adequately described such as sample preparation for performance assessment between analyst, criteria for demonstrating the accurate value of the analyte, statistic technique that used for evaluating such as ISO 13528 or the appropriate statistics, plan and frequency for assessment among the trained analyst, record and report.

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 laboratory shall ensure the evidence of their performance that shall demonstrate on on-site surveillance and re-assessment.

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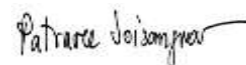
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6.4.2 Frequency in the interlaboratory comparison and the laboratory's performance assessment in test shall be carried out at least once a year or as mentioned in the plan of laboratories. However laboratory shall ensure the evidence of their performance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

6.5 Reporting of proficiency testing / interlaboratory comparison / laboratory's performance assessment in test. Laboratories shall submit the report of those activities to the BLQS-DMSc before an assessment schedule. If the result of proficiency testing is unsatisfactory, laboratories 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 evaluate by the statistic criteria of the proficiency testing provider or using the statistic Z-score according to annex B: statistical methods for proficiency testing (B 4.1.1c) of ISO/IEC 17043: 2010.

$$\begin{array}{l} Z \leq 2 \text{ Satisfactory} \\ 2 < |Z| < 3 \text{ Questionable} \\ |Z| \geq 3 \text{ Unsatisfactory} \end{array}$$

6.5.3 The acceptance criteria for interlaboratory comparison/laboratory's performance assessment in test should depend on the statistical 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 make a decision for the unsatisfactory performance in PT scheme according to the ISO/IEC 17043: 2010 Annex C: selection and use of proficiency testing (C 5.1.4) Of ISO/IEC 17043: 2010, specified that the laboratory 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 to withdraw will depend on the decision making of the Accreditation Committees for testing laboratories or RMP.

7. Data record and used document

- | | | |
|-----|------------|---|
| 7.1 | Appendix 1 | Website of PT providers in medical and public health laboratories |
| 7.2 | Appendix 2 | Accreditation scope discipline |
| 7.3 | Appendix 3 | Actions for accredited laboratories and accreditation bodies |

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8. History of change

Revision No.	Documentation Changes	Prepare /Revised by	Date Issued
00	Initial Document	Panadda Wiroonboonpat	
11	<ul style="list-style-type: none"> - Edited the reference to current (No.3.9) - Edited prepared by /controlled copy list - Added website in appendix 	Saovanee Aromsook	26 OCT 2016
12	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - Edited the reference to current - Added detail of ISO/IEC 17043 	Saovanee Aromsook	12 DEC 2018
14	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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) - Deleted detail no.30 of appendix 1 accordance to ISO/IEC 17025 - Added detail no.10 of appendix 1 accordance to ISO 15189 	Saovanee Aromsook	

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Controlled copy list

- | | |
|--|-----------|
| 1. Director of Bureau of Laboratory Quality Standards (BLQS) | No. 07 00 |
| 2. Head of Laboratory Accreditation Section 1 | No. 07 03 |
| 3. Head of Laboratory Accreditation Section 2 | No. 07 04 |
| 4. Quality Manager of Laboratory Accreditation | No. QM07 |
| 5. Ms. Saovanee Aromsook | |

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Appendix 1

Website: PT providers schemes (Public health laboratory comply with ISO/IEC 17025)

1. Food analysis performance assessment scheme (FAPAS)
www.fapas.com
2. National Association of Testing Authority, Australia (NATA)
www.nata.com
3. American Society of Brewing Chemists, USA
www.asbcnet.org
4. Bureau Interprofessional d'Etudes Analytiques
www.bipea.org
5. Canadian Food Inspection Agency
www.inspection.gc.ca
6. Canadian Association for Laboratory Accreditation. (CALA)
www.cala.ca
7. Institute for Interlaboratory Studies Spijkenisse, The Netherlands.
www.iisnl.com
8. American Optometric Association
www.aoa.org
9. Health Protection Agency Food EQA Schemes, UK
www.hpa.org.uk
12. Laboratory Government Chemist (LGC) Standards' Proficiency Testing, UK
www.lgcgroup.com
13. National Measurement Institute (NMI), Australia
www.measurement.gov.au
14. European Directorate for Quality Medicines and Health Care
www.edqm.eu
15. IFM Quality service Pty., Ltd. (Australia)
www.ifmqs.com.au

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16. American oil chemist society

www.aocs.org

17. American Society

www.asm.org

18. Bureau of Quality and Safety of Food, Department of Medical Sciences, Ministry of Public Health

www.bqsf.dmsc.moph.go.th/bqsfWeb/

19. Institute of Nutrition, Mahidol University.

www.inmu.mahidol.ac.th

20. National Food Institute (NFI)

www.foodfromthailand.com

21. Bureau of Laboratory Accreditation, Department of Science Service

www.dss.go.th/dssweb/bal/index.html

22. Bureau of Cosmetics and Hazardous Substances Control, Department of Medical Sciences, Ministry of Public Health

www.dmsc.moph.go.th/cosmetics/th/home.php

23. Centers of Disease Control and Prevention (CDC)

www.cdc.gov/

24. World Health Organization (WHO)

www.who.int

25. Bureau of Quality Control of Livestock Product, Department of Livestock Development

www.dld.go.th

26. Enersol Consulting Engineers, Australia

www.enersol.com.au

27. Nelson Laboratory, Inc.

www.nelsonlabs.com

28. APAC TEC 2-001 Proficiency Testing Masterlist

www.apac-accreditation.org

29. European Information System on Proficiency Testing Schemes (EPTIS)

www.eptis.bam.de

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Website: แหล่งบริการทดสอบความชำนาญ (ห้องปฏิบัติการทดสอบด้านการแพทย์ ตามมาตรฐาน ISO 15189)

1. European Information System on Proficiency Testing Schemes (EPTIS)
www.eptis.bam.de
2. Bureau of Laboratory Quality Standards, Department of Medical Sciences, Ministry of Public Health
www.dmhc.moph.go.th
3. UK National External Quality Assessment Schemes (UKNEQAS, Clinical laboratory disciplines)
www.ukneqas.org.uk
4. WEQAS Clinical Chemistry (University Hospital of Wales Medical Biological Department Health Park, UK)
www.weqas.com
5. CAP Clinical Chemistry (>100 Programs) (College of American Pathologists, USA)
www.cap.org
6. Australian Institute of Medical Scientists (Immunohaematology)
www.aims.org.au
7. Bio-Rad External Quality Assurances Services
www.bio-rad.com
8. Diagnostic Chemicals Ltd. West Royalty Industrial Park for Veterinary Laboratory
www.delchem.com
9. Toxicology Unit PaLMS Northern Sydney Area Health Service
www.toxicologyunit.com
- ☞ 10. Division of Proficiency Testing DMSc
www.dpt.dmhc.moph.go.th

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Appendix 2

Accreditation scope discipline

1. Biological-General

Sub-disciplines Include:

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

2. Chemical-General

Sub-disciplines:

Chromatography

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

Spectroscopy

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

Titration

1. Potentiometry

Gravimetric

1. Gravimetry

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3. Mechanical

Sub-disciplines:

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

Materials/Matrices/Product Types

1. Foods:

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

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2. Drugs:

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

3. Cosmetics:

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

5. Toxicology:

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

6. Narcotics:

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

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7. Medical materials and medical devices:

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

8. Veterinary diagnostic sample / Livestock products testing:

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

9. Forensic sample:

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

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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.

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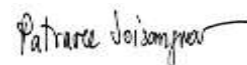
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