ILAC Policies, International Standards, GAC Policies

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2 - Normative references

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Normative References

- Documents indispensible for the application of ISO/IEC 17043
  - ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*
  - ISO/IEC Guide 99:2007, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*
    - *"indispensible for application" does not mean it is followed in all cases – not all PT is measurement*

Informative References

- Documents considered as Normative but are Informational:
  - ISO/IEC 17011
  - ISO/IEC 17025
  - ISO 15189
  - ISO Guide 34
  - ISO/IEC Guide 98-3 (GUM)

Documents for PT Statistics

- ISO/IEC 17043: Conformity Assessment – General requirements for Proficiency Testing (was Guide 43-1)
- ISO 13528 "Statistical Methods for use in Proficiency Testing by Interlaboratory Comparisons
- IUPAC Harmonized Protocol for PT of Chemical Analytical Laboratories, 2006
- APLAC Statistical procedures

ISO/TC 69/SC 6 - Measurement methods and results

Accuracy (trueness and precision) of measurement methods and results

ISO 5725-1:1994
-- Part 1: General principles and definitions
ISO 5725-2:1994
-- Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method

ISO 5725-3:1994
ults -- Part 3: Intermediate measures of the precision of a standard measurement method

ISO 5725-4:1994
-- Part 4: Basic methods for the determination of the trueness of a standard measurement method

ISO 5725-5:1998
-- Part 5: Alternative methods for the determination of the precision of a standard measurement method

ISO 5725-6:1994
-- Part 6: Use in practice of accuracy values

ISO 13528:2005
Statistical methods for use in proficiency testing by interlaboratory comparisons
ISO/TR 22971:2005
Accuracy (trueness and precision) of measurement methods and results -- Practical guidance for the use of ISO 5725-2:1994 in designing, implementing and statistically analysing interlaboratory repeatability and reproducibility results

ISO 11843-2:2000
Capability of detection -- Part 2: Methodology in the linear calibration case

ISO 11843-3:2003
Capability of detection -- Part 3: Methodology for determination of the critical value for the response variable when no calibration data are used

ISO 11843-4:2003
Capability of detection -- Part 4: Methodology for comparing the minimum detectable value with a given value

ISO 11843-5:2008
Capability of detection -- Part 5: Methodology in the linear and non-linear calibration cases

ISO 11843-6:2013
Capability of detection -- Part 6: Methodology for the determination of the critical value and the minimum detectable value in Poisson distributed measurements by normal approximations

ISO 11843-7:2012
Capability of detection -- Part 7: Methodology based on stochastic properties of instrumental noise

ISO/TR 13587:2012
Three statistical approaches for the assessment and interpretation of measurement uncertainty

ISO 21748:2010
Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation

ISO/TS 21749:2005
Measurement uncertainty for metrological applications -- Repeated measurements and nested experiments

ISO/TS 28037:2010
Determination and use of straight-line calibration functions

ISO 10576-1:2003
Statistical methods -- Guidelines for the evaluation of conformity with specified requirements -- Part 1: General principles

ISO 10725:2000
Acceptance sampling plans and procedures for the inspection of bulk materials

ISO 11095:1996
Linear calibration using reference materials

ISO 11648-1:2003
Statistical aspects of sampling from bulk materials -- Part 1: General principles

ISO 11648-2:2001
Statistical aspects of sampling from bulk materials -- Part 2: Sampling of particulate materials

ISO 11843-1:1997
Capability of detection -- Part 1: Terms and definitions

History of Standards for Proficiency Testing

- 1945-1982 Interlaboratory Comparisons
  - Method validation
  - Material verification
  - 1964 PT (US medical –CAP, 1968)
- 1984 ISO/IEC Guide 43 1stEdition
- 1993 IUPAC Harmonized Protocol
- 1997 ISO/IEC Guide 43-1 and 43-2

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History of Standards for PT

- 2000: ILAC G13
  - Management system from ISO/IEC Guide 25
  - Technical requirements from Guide 43-1
    - Replace “should” with “shall”
    - Edit informative discussion in Guide 43
- 1997-2005 ISO 13528 on *Statistical Methods for PT by ILC*
- 2006: IUPAC Harmonized Protocol

History of Standards for PT

- 2007: ILAC G13
  - Update Management Requirements
  - Remove redundant requirements
  - Add language for medical EQA/PT
- 2010: ISO/IEC 17043
  - Requirements for competence
  - PT is conformity assessment activity
  - Revisions to G13, Guide 43

ILAC Policies

- **ILAC P9:11/2010 ILAC Policy for Participation in Proficiency Testing Activities**

This document sets out the policy for accreditation bodies on the use of proficiency testing activities in the accreditation process.

- **ILAC P13:10/2010 Application of ISO/IEC 17011 for the Accreditation of Proficiency Testing Providers**

The aim of this document is to harmonise the application of ISO/IEC 17011 for accreditation bodies in regard to organising proficiency testing programs and/or accrediting Proficiency Testing Providers.

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ILAC Policy for Participation in Proficiency Testing Activities

- MRA Expansion

- ***ILAC Resolution GA11.21***

The ILAC General Assembly,… agrees to proceed with an expansion of the scope of the ILAC MRA to include accredited PT scheme providers

ISO/IEC 17043 -Use

- ***ILAC Resolution GA13.27***
- Referencing ILAC GA Resolutions GA 9.12 and 9.13, and recognising that ILAC has played a significant role in the creation of a draft International Standard for Proficiency Testing, the General Assembly endorses the use of ISO/IEC 17043, when published, for the accreditation of Proficiency Testing Providers
- Effective two year after publication of ISO/IEC 17043, the General Assembly withdraws its endorsement of the use of ILAC G13 and ISO/IEC Guide 43 as referenced in GA Resolution 9.13 and approves the withdrawal of ILAC G13

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ISO/IEC 17043 –ISO 13528

- ***ILAC Resolution GA13.28***
- Taking into account the anticipated publication of ISO/IEC 17043, and the need for ILAC members to use current and appropriate statistical methods for analysing proficiency testing data, the General Assembly requests a review of ISO 13528 Statistical methods for PT by Interlaboratory comparison by ISO TC69

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ILAC Proficiency Testing Working Group

- **ILAC Resolution GA 16.26**
- The General Assembly agrees that the Proficiency Testing Consultative Group will be disbanded and reconstituted as a Proficiency Testing Working Group under the Accreditation Committee (AIC).
- Commencing in 2013, meetings of the working group will occur annually in conjunction with the AIC mid-year meetings, and participation will be open to all interested ILAC members and stakeholders as well as PT providers

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ILAC Policy for Participation in Proficiency Testing Activities

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Requirements ILAC P9

- Previous (P9:2005): One activity prior to gaining accreditation;
- One activity relating to each major sub discipline within every four years

- Current (P9:2010)evidence of satisfactory participation prior to gaining accreditation;
- further and ongoing activity that is “fit for purpose” and appropriate to the technical discipline(s) covered by the scope of accreditation.

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Requirements ILAC P9

- ILAC P9:2010 -Approach
- Removes concept of “major sub disciplines” (difficult to apply consistently)
- References APLAC PT006 and EA 4/18 as viable approaches
- Encourages use of EPTIS and other relevant sources of information about PT

Requirements ILAC P9

- Current (P9:2010) –Implementation Laboratory to develop a PT Plan, to be approved by Accrediting Body
- Europe: Lab to develop own sub-disciplines based on guidance in EA 4/18
- GAC policy on PT and technical note 4

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ILAC P9: When PT not available

Other activities allowed :

- Participate in other ILC
- Certify reference materials
- Validate methods
- Bilateral comparisons with other laboratories (split sample programs)

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ILAC P9: When PT not available

- Other activities allowed :Measure CRMs as trueness check
- Reanalysis of retained samples (less preferred)
- Reanalysis with second measurement procedure (less preferred)

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APLAC PT publications

- Documents prepared by the APLAC Proficiency Testing Committee to assist members and others with the conduct of proficiency testing programs.
- APLAC PT001 APLAC Calibration Interlaboratory Comparisons
- APLAC PT 002 APLAC Testing Interlaboratory Comparisons
- APLAC PT 003 APLAC Proficiency Testing Directory
- APLAC PT 004 APLAC Measurement Audits - Withdrawn
- APLAC PT 005 Artefacts for Measurement Audits
- APLAC PT 006 Proficiency Testing Frequency Benchmarks

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APLAC
Asia Pacific Laboratory Accreditation Cooperation

PROFICIENCY TESTING FREQUENCY BENCHMARKS

APLAC PT 006 Benchmarks

- Frequencies for different areas of testing and calibration: Medical: 10/year
- Chemical (environmental and mineral): 2/yr
- Biological: 2/yr
- Forensics, chemical, veterinary: 1/yr
- Specific Calibration fields: 1 per 2 years

PROFICIENCY TESTING FREQUENCY BENCHMARKS

- APLAC PT 006
- The accreditation body's PT policy should focus on more than just meeting the requirements as stated in ILAC-P9. The accreditation body should ensure participation when PT is available, appropriate and at a frequency that reflects best practices and/or best local norms. When determining the appropriate frequency of PT, the accreditation body should take into account the test range, method capabilities and regulatory limits, where available.

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European co-operation for Accreditation

EA-4/18 INF: 2010

Guidance on the level and frequency of proficiency testing participation

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EA 4/18 – EA Policy

- EA-4/18:2010 *Guidance on the level and frequency of proficiency testing participation*
- Laboratory to determine sub-disciplines for PT based on different competencies in scope
- Laboratory to determine frequency of PT based on risk, availability, and other QA activities
- Laboratory to choose PTs to participate in
- Accrediting Body to review and approve laboratory PT Plan (or not approve)

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EA-4/18:2010 -Definitions

- **Sub-discipline:** An area of technical competence defined by a minimum of one Measurement Technique, Property and Product, which are related.
- **Level of Participation:** The number of sub-disciplines that an organization identifies within its scope, and therefore the number of specific proficiency tests that should be considered for participation
- **Frequency of Participation:** This is how often a laboratory determines that it needs to participate in PT for a given sub-discipline, this may vary from sub-discipline to sub-discipline within a laboratory and between laboratories with the same sub-disciplines

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EA-4/18 –Level and Frequency

- Once sub-disciplines are defined, the “level of participation” has been defined.
- Laboratories will also determine a minimum “frequency” of participation for each sub-discipline, based on level of risk.
- ABs need to evaluate the suitability of the laboratory’s “frequency”, based on level of risk.

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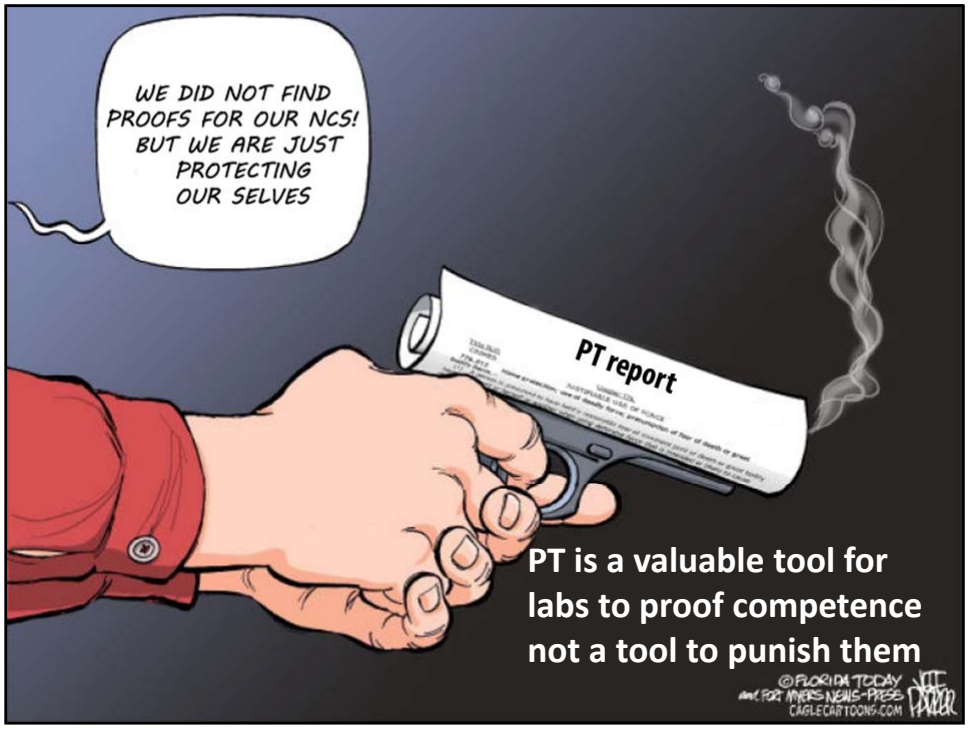

GAC Proficiency Testing policy

BD-091007-08-04	GAC
GAC Technical Note 4 Proficiency testing	مركز الإعتماد الخليجي GCC ACCREDITATION CENTER

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Proficiency Testing policy

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Participation in PT programs

- Each applicant or accredited CAB is required to participate in proficiency testing programs. Participation in proficiency testing may be required as follows:
  - prior to gaining accreditation with GAC;
  - as requested by the GAC Service Delivery Manager;
  - when requesting extensions and/or variations to the scope of accreditation.
- CABs are encouraged to participate in as broad a range of proficiency testing activities as practicable and are available. Once every two years is advisable for each major area of test or measurement.
- Where a proficiency testing program is not available for an activity covered by the scope of accreditation, the CAB must demonstrate how it maintains confidence in its results. Participation in intra or inter-laboratory programs should also be considered e.g. sample exchange.

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Selection of Proficiency Testing Providers

- CABS should select proficiency testing providers taking into account the following points:
- the CAB is to determine which provider(s) best suits its needs i.e. scope;
- where possible, the provider should be accredited as fulfilling the requirements of ISO/IEC 17043; and
- where not accredited, the CAB should satisfy itself that provider meets the requirements of ISO/IEC17043.

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Performance in programs

- Performance in proficiency testing programs is reviewed during the on-site assessment (unless for specific identified programs - In those cases feedback on participant performance is required to be provided to the GAC at the same time the results are forwarded to participants).
- The GAC may seek an immediate comment on the corrective action taken where necessary.
- The GAC will review each applicant or accredited CABs response and either accept that the problems have been resolved and require no further action or take further action where applicable.
- Further action may include:
  - requiring further proficiency testing;
  - suspending all or part of the accreditation; or
  - undertaking a partial or full assessment.

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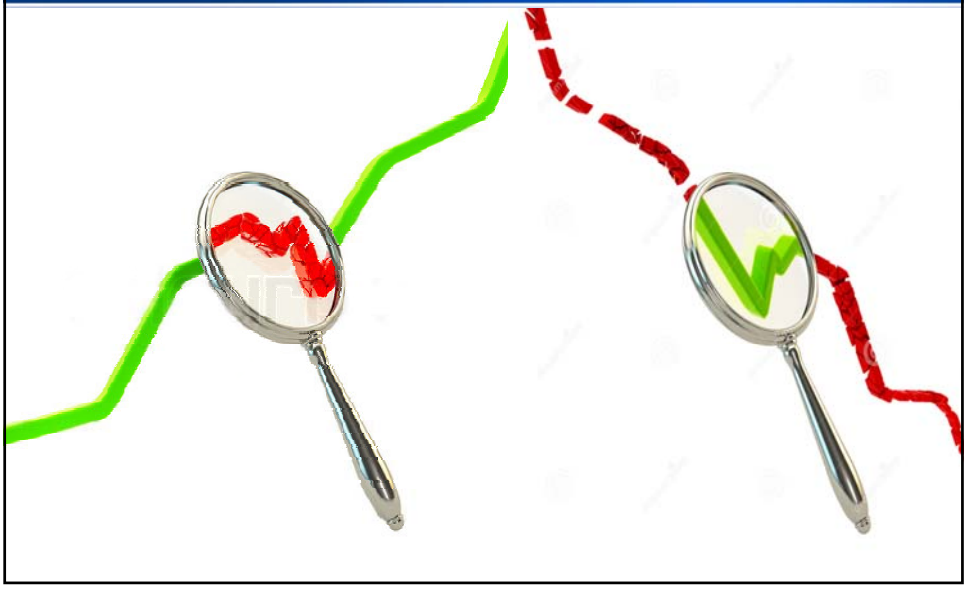
Use of proficiency testing



Laboratory Responsibilities

- Selection of PT Scheme
- Running PT tests and calibrations
- Interpreting reports
- Interpreting performance evaluations
- Corrective action
- Preventive action
- Communication with PT/EQA provider

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Selection of PT Scheme

- Approved by Accrediting Body and/or Regulatory Agency
- Accredited by recognized ILAC Member
- Appropriate analytes or measurements, ranges, frequencies for laboratory needs
- Affordable
- Appropriate assigned values and performance evaluation criteria
- Good customer relations

Selection of PT Scheme

- NOTE Some proficiency testing schemes can include tests which are not an exact match for the tests performed by the participant (for example, the use of a different national standard for the same determination) but it can still be technically justified to participate in the proficiency testing scheme if the treatment of the data allows for consideration of any significant differences in test methodology or other factors.

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Running PT

- Follow PT provider's instructions
- Use routine methods, unless….
- Don't cheat (ask other participants, refer PT item, test or measure in special ways)
- Use all operators and all equipment
- Be careful in reporting results
- Report on time

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Interpreting Reports

- Make sure lab results are correct
- Look at warning and action signals
- Monitor acceptable results also for bias
- Review results from other participants
- Review results from other methods
- Review technical comments
- Review results from previous rounds

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