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LABORATORIES PROFICIENCY

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# **ISO/IEC 17043 Conformity assessment – General requirements for proficiency testing**

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# Brief History of PT Standards

- 1945-1982 Interlaboratory Comparisons
  - Method validation, reference material verification
  - 1963 PT (US medical – CAP)
- 1984 ISO/IEC Guide 43 1<sup>st</sup> Edition
- 1993 IUPAC Harmonized Protocol (1<sup>st</sup> version)
- 1997 ISO/IEC Guide 43-1 and 43-2
- 2000: ILAC G13 (1<sup>st</sup> version)
- 2006: IUPAC Harmonized Protocol (2<sup>nd</sup> version)
- 2007: ILAC G13 (2<sup>nd</sup> version)
- 2010: ISO/IEC 17043



# Related PT Standards

- 2005: ISO 13528: Statistical methods for use in proficiency testing by interlaboratory comparisons
  - From ISO Technical Committee 69: *Application of Statistical Methods*
  - Follows ISO Guide 43-1 (1997)
  - Currently under revision (2014?)
- 2011: Eurachem Guide - Selection, Use and Interpretation of Proficiency Testing (PT) Schemes by Laboratories



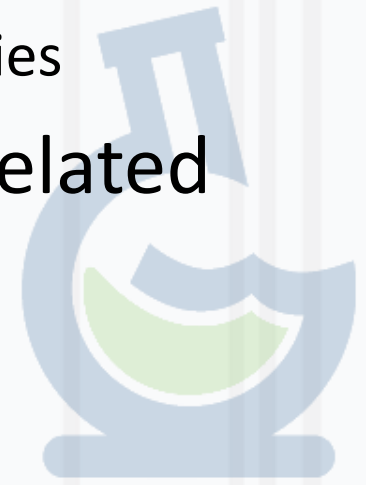
# Fundamentals of ISO/IEC 17043

- Management System Requirements similar to ISO/IEC 17025
  - Updated to conform to ISO 9001: 2008
- Technical Requirements revised from ILAC G13:2007 and ISO Guide 43-1
- Three Informative annexes
  - A: Types of proficiency testing schemes
  - B: Statistical methods for proficiency testing
  - C: Selection and use of proficiency testing



# Fundamentals of ISO/IEC 17043

- Standard is from ISO Conformity Assessment Committee (CASCO)
  - PT is “conformity assessment activity”
  - CASCO Neutrality Policy applies
    - No requirement for means of recognition of conformance
    - No requirement for accreditation of laboratories
- Can be confusing for interpretation of related Standards from other ISO Committees
  - Technical Committees (e.g., ISO TC69)
  - REMCO (especially ISO Guides 34 and 35)



# Scope

- Requirements meant to apply broadly
  - Testing and calibration laboratories
  - Inspection bodies
  - Individuals
  - Includes PT for sampling
- Normative documents
  - ISO/IEC 17000: 2004 Conformity assessment
  - ISO/IEC Guide 99:2007 (VIM)



# Definition of Proficiency Testing

- Evaluation of participant performance against pre-established criteria by means of **interlaboratory comparisons**
  - Quantitative or qualitative
  - Sequential or simultaneous
  - Single occasion or continuous
  - Sampling, data transformation, interpretation





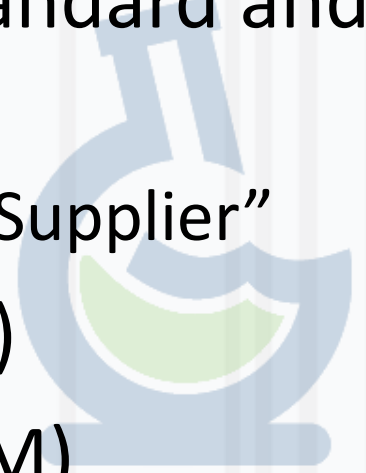
# Definition of ILC

- **Interlaboratory comparison:** “organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions”
- **PT (and ILC):**
  - Predetermined conditions of operation
  - Two or more laboratories
  - Predetermined criteria for evaluation



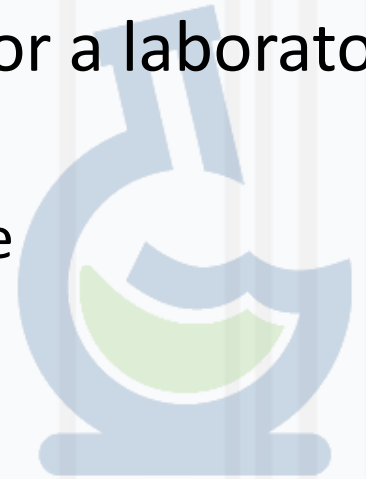
# Definitions of Interest

- **Customer:** has a contractual arrangement with PTP
- **Outlier:** statistical definition (not just  $z > 3$ )
- **Participant:** laboratory, organization, or individual
- **Subcontractor:** organization or individual engaged... to perform activities specified in the Standard and that affect quality of the PT scheme
  - Sometimes difficult to differentiate from “Supplier”
- **Metrological traceability** (same as VIM)
- **Measurement uncertainty** (same as VIM)



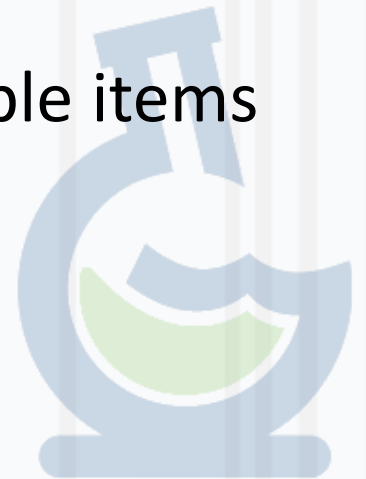
# Management System Requirements

- A few important differences
  - **5.1.4**, impartiality: recognizes that PT providers might be associated with an accredited laboratory, or an organization that has competitors
  - **5.1.5**, expertise – have access to statistical expertise
  - **5.5**, subcontracting is very different than for a laboratory
    - Demonstrate competence of subcontractor
    - Can not subcontract areas of core competence
      - Design/planning
      - Evaluation of performance
      - Release of final reports



# Technical Requirements - Highlights

- **4.2.4** Specific authorizations of personnel (a-k)
- **4.4.1** Planning as a core competence (a-u)
- **4.4.3** Homogeneity and stability
  - Criteria based on the effect on evaluation (not statistical significance)
  - Possible to have inhomogeneous or unstable items



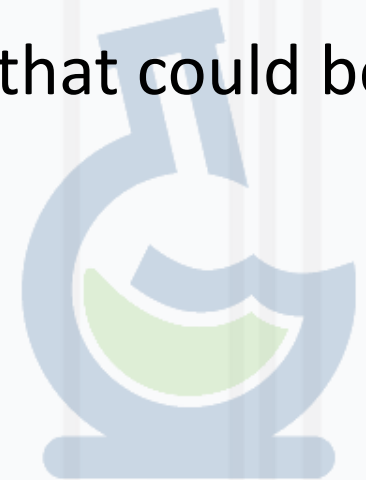
# Technical Requirements - Highlights

- 4.4.4 Statistical design
  - Meet objectives of scheme
    - Compare participants with each other?
    - Compare results with reference values?
    - Compare results with claimed uncertainty?
  - Nature of data
  - Statistical assumptions
  - Number of observations



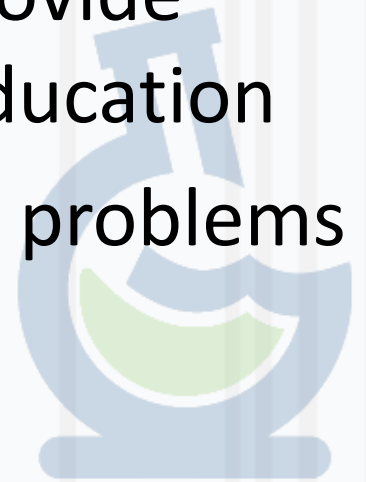
# Technical Requirements - Highlights

- **4.4.5 Assigned values**
  - Consider metrological traceability
    - Required in PT for calibration
    - Appropriate traceability in testing
- **4.5 Choice of method or procedure**
  - PT provider must understand all methods that could be used by participants
    - Which methods are equivalent?
  - Evaluate results appropriately



# Technical Requirements - Highlights

- **4.7.2 and 4.8:** Technical interpretation
- CASCO WG28 members all agreed that the most important purpose for PT is a tool for laboratory improvement.
- Regulatory & accreditation purposes provide motivation, but can get in the way of education
- PT providers see all methods, see many problems
  - Share that information in reports



*Thank you for attention,  
and for participation in this conference*

