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

6th Eurachem Workshop

7 October, 2008

Daniel Tholen, M.S.

A2LA, APLAC, ILAC

Background: ISO/IEC 17043

- ❑ Work Proposal from ILAC, 2006 to revise ISO/IEC Guide 43-1 and 43-2

- ❑ In addition to Guide 43, use ILAC G13 and IUPAC as base documents.

- ❑ Approved by CASCO; solicited experts for Working Group 28 (WG28)

- ❑ 59 experts on WG28, 30 CASCO member countries and 5 liaison organizations

WG28 – Americas, Asia and Africa

- Argentina
- Brazil
- Canada
- Columbia
- Mexico
- Peru
- Trinidad and Tobago
- United States

- Australia
- China
- India
- Indonesia
- Japan
- Malaysia
- Singapore
- Thailand
- South Africa

WG28 – Europe & Liaisons

- Austria
- Belarus
- Czech Republic
- Denmark
- France
- Germany
- Ireland
- Italy
- Netherlands

- Spain
- Sweden
- Switzerland
- United Kingdom

Liaisons:
  - BIPM
  - IEC
  - ILAC
  - UILI
  - CODEX Alimentarius

WG28 Progress

- 1st Meeting December 2006
  - Outcome: WD1
- 2nd Meeting May, 2007
  - Outcome: WD2, WD3
  - 211 comments received from WG members
- 3rd Meeting January, 2008
  - Outcome: CD
  - Ballot CD March-June, 2008

WG28 progress

- CASCO ballot of 72 P members
  - 49 "approve" or "approve with comment"
  - 0 members: "disapprove"
  - 6 members: "abstain"
  - 488 comments received
- 4th meeting, 3-5 September, 2008
  - All comments resolved
  - No outstanding disagreements
  - Outcome: recommendation to proceed as DIS
- DIS released Nov/Dec 2008, 5 month ballot
- 5th (last?) meeting ~July, 2009
- FDIS ballot Sept-Oct, 2009

17043 General Format

- Language and requirements in alignment with ISO/IEC 17025

- Management System Requirements conform for content per ISO PAS 17005

- Structure not consistent with ISO 17005

- No reference to a particular means of recognition of competence of providers, laboratories and subcontractors:

  "This International Standard has been prepared to provide a consistent basis for all interested parties to determine the competence of organizations that provide proficiency testing."

17043 General Format

- Scope of document is expanded:

From the Introduction: *"There is a growing need for proficiency testing for other conformity assessment activities, such as inspection or product certification. Most of the requirements in this International Standard apply to those evolving areas, especially regarding management, planning and design, personnel, assuring quality, confidentiality, and other aspects as appropriate."*

Structural changes from G13 and Guide 43 parts 1 and 2

- Technical Requirements come before Management Requirements
- One part with 3 Informative Annexes rather than two parts

    A: Types of proficiency testing

    B: Statistical methods for proficiency testing

    C: Selection and use of proficiency testing

ISO/IEC 17043 Scope

This International Standard specifies general requirements for the competence of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes. These requirements are intended to be general for all types of proficiency testing schemes, and they can be used as a basis for specific technical requirements for particular fields of application.

Definitions – What is it ?

- **proficiency testing** – evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons
  - Quantitative / qualitative
  - Single item (sequential) / bulk interlaboratory
  - Single occasion / continuous
  - Sampling
  - Data transformation and interpretation

Definitions – What is provided?

- **proficiency testing scheme -** proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection

- **proficiency test item -** sample, product, artefact, reference material, piece of equipment, measurement standard, data set or other information used for proficiency testing

Definitions – Who's involved?

- **proficiency testing provider** – organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme

- **participant** – laboratory, organization or individual, that receives proficiency test items and submits results for review by the proficiency testing provider

    NOTE   In some cases the participant may be an inspection body

Definitions – who else?

- **coordinator -** one or more individuals with responsibility for organizing and managing all of the activities involved in the operation of a proficiency testing scheme

- **customer -** organization or individual for which a proficiency testing scheme is provided through a contractual arrangement

- **subcontractor** – organization or individual engaged by the proficiency testing provider to perform activities specified in this International Standard and that affects the quality of a proficiency testing scheme

Definitions - statistics

- **assigned value** – value attributed to a particular property of a proficiency test item.

- **outlier** - observation in a set of data that appears to be inconsistent with the remainder of that set

  NOTE - An outlier can originate from a different population or be the result of incorrect recording or other gross error.

  … this makes it inappropriate to use the term "outlier" for a result outside the acceptance limit (e.g., z score >3); … we eliminated the term "extreme result" (Guide 43)

Definitions – from VIM, with Notes

- **metrological traceability -** property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty (+8 Notes)

- **measurement uncertainty -** non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used (+4 Notes)

Content changes from Guide 43-1 and ILAC G13 - 2007

- Removed G13 requirements to assess safety standards
  - Retain requirements for safe handling, decontamination and disposal of potentially hazardous proficiency test items (4.6.2.4).
- Enhanced requirements to promote educational potential of PT.

Content changes from G13 and Guide 43

- Move "Collusion and falsification of results" into Technical Requirements sections on Design (4.4.1.3, i) and Instructions (4.6.1.2, d)

- Relate criteria for homogeneity and stability (4.4.3) to the effect on evaluation of performance

Content changes from Guide 43-1 and ILAC G13 - 2007

- Added requirements that some tasks *shall not* be subcontracted (5.5.2)
  - Planning PT scheme (4.4.1.2)
  - Evaluating performance (4.7.2.1)
  - Authorizing final reports (4.8.1)
- Add requirements for equipment in 4.3, similar to17025

Changes – Choice of method

- **4.5.2** Where participants are permitted to use a method of their choice, the proficiency testing provider shall have a policy and follow a documented procedure regarding comparison of results obtained by different test or measurement methods.

  The proficiency testing provider shall be aware of which different test or measurement methods for any measurand are technically equivalent, and take steps to assess participants' results using these methods accordingly.

Changes – 4.8 Reports

(New section, to highlight the importance of the main product of proficiency testing; drop the phrase "shall normally").

- **4.8.2** Reports shall include the following unless it is not applicable or the proficiency testing provider has valid reasons for not doing so:
  - o) assigned values and summary statistics for methods/procedures used by each group of participants
  - p) comments on participants' performance
  - t) comments or recommendations, based upon the outcomes of the proficiency testing round

Traceability and Uncertainty

- **4.4.1.3** The proficiency testing provider shall document a plan before commencement of the proficiency testing scheme that shall address the following information and, where appropriate, reasons for its selection or exclusion:

  q) the origin, *metrological traceability and measurement uncertainty* of any assigned values;

- **4.4.5.1** The proficiency testing provider shall document the procedure for determining the assigned values for the measurands or characteristics in a particular proficiency testing scheme. This procedure shall take into account the *metrological traceability and measurement uncertainty* required to demonstrate that the proficiency testing scheme is fit for its purpose.

Traceability and Uncertainty

- **4.7.2.2**   Where appropriate for the purpose of the proficiency testing scheme, the proficiency testing provider shall provide expert commentary on the performance of participants with regard to the following:

  a) overall performance against prior expectations taking *measurement uncertainties* into account;

- **4.8.2**   Reports shall include the following unless it is not applicable or the proficiency testing provider has valid reasons for not doing so:

  – m) details of the metrological *traceability and measurement uncertainty* of any assigned value

Changes - Assigned Value

- **4.4.5.1** The proficiency testing provider shall document the procedure for determining the assigned values for the measurands or characteristics in a particular proficiency testing scheme.

  This procedure shall take into account the metrological traceability and measurement uncertainty required to demonstrate that the proficiency testing scheme is fit for its purpose.

Changes - Assigned Value

- **4.4.5.2** Proficiency testing schemes in the area of calibration shall have assigned values with metrological traceability, including measurement uncertainty.

(no consensus values in calibration PT)

Changes - Assigned Value

- **4.4.5.3** For proficiency testing schemes in areas other than calibration, the relevance, needs and feasibility for metrological traceability and associated measurement uncertainty of the assigned value shall be determined by taking into account specified requirements of participants or other interested parties, or by the design of the proficiency testing scheme.

Changes - Assigned Value

- **4.4.5.4** When a consensus value is used as the assigned value (see Annex B), the proficiency testing provider shall document the reason for that selection and shall estimate the uncertainty of the assigned value as described in the plan for the proficiency testing scheme.

Changes – 4.9 Communications

- **4.9.5.** If the proficiency testing provider issues statements of participation or performance, they shall contain sufficient information to not be misleading.

    …based on a comment and confirmed by several WG members' experiences.

Annex A: Types of proficiency testing

- Revised from introductory language in ISO/IEC Guide 43-1
- Provides further explanation of NOTES in the definition of PT
  - Sequential schemes
  - Simultaneous schemes
    - EQA
    - Split level
    - Split sample
    - Partial process
    - Blind

Annex B: Statistical methods for proficiency testing

- Reference ISO 13528 and 2006 IUPAC Harmonized Protocol
- Provide further discussion of statistical methods for qualitative and ordinal results
  - Simple listing of categorical responses
  - Don't take average of numeric ordinal data
- D, D%, Z score, E_n, zeta
- ISO TC69/SC6 consulted

Annex C: Selection and Use of Proficiency Testing

- Based on Guide 43-2.
- Separate sections for laboratories and for "interested parties"
  - Accreditation bodies
  - Regulatory agencies
  - Laboratory Customers
- Very general guidance on recognition of competence and use of results
- Considerations for accreditation bodies to be addressed by revised ILAC P9

Next steps

- Editing by CASCO and ISO
- Release DIS to ISO and IEC members for ballot - 5 month period for ballot and comment.
- WG convene to discuss ballot and resolve comments. If the ballot was successful and the WG agrees on all revisions, issue FDIS for vote by ISO & IEC as approved International Standard - 2 month period

Acknowledgements

- ILAC – for the Work Item Proposal, support for experts
- A2LA – support for my time and expenses
- WG28 Experts – review, comment, management of mirror committees, and attendance at meetings.

- EEE-PT – for continued advice, support, and advocacy
- ILAC PTCG – for revision of G13
- APLAC PT Committee – expertise, application

- ISO TC69 – statistical review
- CASCO Secretariat – support and guidance

Acknowledgements

- WG28 Drafting Committee:
  - Robert Audette – Canada
  - Brian Brookman – UK
  - Jane Gun-Munro – Canada
  - Jeff Gust – USA
  - Ian Mann – Switzerland
  - Christophe Perruchet – France
  - Tony Russell – Australia
  - Steve Sidney – South Africa
  - Lorraine Turner – UK
  - Peter vandeLeemput – Netherlands

Thank you for listening and for...
any Comments or Questions?