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A2LA



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ISO/IEC 17043 Proficiency Testing

Presented by: Kelly Black
Neptune and Company, Inc.
A2LA Assessor / Statistician

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Overview

- History of Proficiency Testing Standards
- ISO/IEC 17043:2010 –Contents
- Benefits of Proficiency Testing to Customers



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ISO 17011 – Requirements for Accreditation Bodies

- 7.15 The accreditation body ...
 - 7.15.1 ...shall take into account the laboratory's performance in proficiency testing.
 - 7.15.2 may conduct proficiency testing itself... it shall maintain a list of proficiency testing bodies judged to be competent.
 - 7.15.3... shall ensure that its accredited laboratories participate in proficiency testing.
 - ...or other comparison programs...or other surveillance activities



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ISO 17011 – Requirements for Accreditation Bodies

- 4.3 Impartiality
- 4.3.6 The accreditation body shall not offer or provide any service that affects its impartiality, such as...
 - a) those conformity assessment activities that CABs perform, or
 - b) consultancy



History of Standards for PT

- 1945-1982 Interlaboratory Comparisons
 - Method validation, Material verification, 1964 PT (US medical – CAP, 1968)
- 1984 ISO/IEC Guide 43 1st Edition
- 1993 IUPAC Harmonized Protocol
- 1997 ISO/IEC Guide 43-1 and 43-2
 - Proposed by ILAC (ASTM E1301)



History of Standards for PT (cont.)

- 2000 ILAC Guide I 3
 - Management system from ISO/IEC Guide 25
 - Technical requirements from ISO Guide 43-1 (edit should = shall); no informative text.
- 2005 ISO 13528 on Statistical Methods for PT by interlaboratory comparison
- 2006 IUPAC Harmonized Protocol #2
- 2007 ILAC Guide I 3 revision



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ILAC G13:2007

- Management system from ISO/IEC 17025:2005
- Technical requirements revised slightly from 2000
 - Eliminate redundant requirements
 - Clarify wording
 - Considerations for medical EQA
- No** controversial changes from version 1 to version 2.



2010 ISO/IEC 17043

- ❑ Revision of ISO/IEC Guide 43-1 and 43-2
- ❑ In addition to Guide 43, used ILAC GI3 and IUPAC as base documents.
- ❑ Approval CASCO, solicitation of experts for Working Group 28 (WG28)
- ❑ 61 experts on WG28, 30 CASCO member countries and 4 liaison organizations





ISO/IEC 17043 Scope

- General requirements for the **competence** of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes





PT Provider Accreditation

- Currently offered by Accreditation Bodies including:
 - 10 APLAC members
 - 7 EA members, SANAS



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ISO/IEC 17043 - Content

- Management System from ISO 17025
 - Consistent with ISO 9000 & ISO/IEC 17025
- Technical Requirements from G13:2007
- Scope expanded to include inspection bodies, sampling



ISO/IEC 17043 - Content

- Switch order – Technical Requirements before Management Requirements
- Annex A on Types of Proficiency Testing
- Annex B on Statistical Methods
 - Similar to Guide 43-1 Annex A
 - Reference ISO 13528 and IUPAC Harmonized Protocol (2006)
 - Assistance from ISO TC69



ISO/IEC 17043 - Organization and Management

- Organization requirements
- Management system
- Document control
- Review of Requests, tenders and contracts
- **Subcontracting Services**
- Purchasing services and supplies
- Service to customers



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ISO/IEC 17043 contents- Management System

- Complaints and appeals
- Control of non-conforming work
- Improvement
- Corrective actions
- Preventive actions
- Control of records
- Internal audits
- Management reviews



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Subcontracting services

- Departs from subcontracting as we know it in the laboratory testing community where the subcontracting is usually for the entire testing process. For a subcontracted test to be on a laboratory's scope of accreditation, the lab must be able to demonstrate that they are technically competent to perform that test.
- Subcontracting for proficiency testing providers usually is for a specific task within the operation of a proficiency testing scheme.



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Subcontracting Limitations

- ISO/IEC 17043 prohibits the following activities from being subcontracted:
 - Planning of the proficiency testing scheme
 - Evaluation of laboratory performance
 - Authorization of the final report issue

- The proficiency testing provider is to inform participants, in advance and in writing, of services that are subcontracted



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ISO/IEC 17043 Technical Requirements

- Technical requirements are what separates **Accreditation** to ISO/IEC 17043 from **Certification** to ISO 9001. The applicant must demonstrate their technical competency of specific tasks.



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Personnel

- The proficiency testing provider shall have managerial and technical personnel with:
 - Authority
 - Resources
 - technical competence required to perform their duties



Equipment, accommodation and environment

- Appropriate facilities and equipment for:
 - manufacturing, handling, calibration, testing, storage and dispatch, data processing, communications, recordkeeping
- Control access to areas affecting the quality of PT schemes
- Control and monitor conditions, and shall record all relevant monitoring activities. PT activities stopped when conditions are outside prescribed specifications



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Design of PT Scheme

- Planning
- Preparation of PT Schemes
 - establish and implement procedures to ensure appropriate acquisition, collection, preparation, handling, storage and, where required, disposal of all PT items
 - PT items should match in terms of matrix, measurands and concentrations, the type of items in their customers routine testing



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PT Design

■ Homogeneity and Stability Assessment

- Procedures for the assessment of homogeneity and stability shall be documented in accordance with appropriate statistical designs
- Homogeneity testing shall normally be performed after the PT items have been packaged in the final form and before distribution to participants
- PT items shall be stable to ensure that they will not undergo any significant change during participants proficiency testing, and during storage and transport



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Assigned Values

- The PT Provider must have a procedure for determining the assigned values for the measurands or characteristics in a particular PT scheme. PT Provider must take into account metrological traceability and measurement uncertainty required to demonstrate that the PT is fit for its purpose.
- Requirements for when using consensus values





Choice of Method or Procedure

- Requirements for provisions for participants in using methods/procedures of their choosing
- PT Provider shall have procedures to address use of participants different methodologies





Operation of PT Schemes

- PT Providers shall provide detailed, documented instructions to participants
- PT Providers shall ensure items are protected from contamination/degradation
- PT Provider shall ensure appropriate packaging and labeling



Data Analysis and Evaluation of Results

- PT Provider have provisions in place for validation of data processing equipment and software and back up process for computer systems
- Participant results shall be recorded and analyzed by appropriate methods
- Summary statistical data analysis
- Description of the basis for the evaluation of participants results



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Reports and Communications with Participants

- Reports shall be clear and comprehensive and include data covering the results of all participants, together with an indication of the performance of individual participants
- PT Provider shall make information available on the scope and fees of the PT scheme, eligibility criteria
- Instructions for participants on how to appeal results
- Participation information confidential unless they

consent



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Why “*General* Requirements”?

- Intended to be general so that they can be applied to ALL types of PT schemes:

Medical

Food

Environmental

Electrical

Veterinary

Calibration

Forensics

Construction Materials/
GeoTech



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Why “*General* Requirements”?

- Specific technical requirements can then be added to these minimum general requirements for particular fields. A great example is the TNI Requirements are added to ISO/IEC 17043 for the Environmental Proficiency Testing Schemes.
- **Accreditation Bodies can cater programs to specific technical groups needs**



Benefits of ISO/IEC 17043:2010 Accreditation

- PT Providers receive
 - an external “check” on their systems
 - a credential for use for marketing / business expansion
- Laboratories receive
 - assurance of technical competence in a PT provider



Benefits of ISO/IEC 17043:2010 Accreditation (cont.)

- Government/industry specifiers receive
 - assurance of technical competence in a PT provider
 - effective oversight of program that they rely on so that they can direct attention on other programs like regulations, permitting.



Points of Contact

- Kelly Black – President
Neptune & Co, Inc.
Email: kblack@neptuneinc.org
Phone: 720-746-1803
- Robert Knake – A2LA Sr.
Accreditation Officer
Email: rknake@A2LA.org
Phone: 301-644-3128
Web: www.A2LA.org
- Randall Query –
A2LA Life Sciences
Accreditation Manager
Email: rquery@A2LA.org
Phone: 301-644-3221
Web: www.A2LA.org



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