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

R. Borroni, G. Ciccgionli, M. Patriarca
ISO/IEC 17043: Introduction

- ISO/IEC 17043 provides a consistent basis for all interested parties to determine the competence of organizations that provide proficiency testing (PT).
- PT organisation is one of the tasks of EU-RL and NRL (Article 32-33 of Reg. (EC) 882/2004)
- Participation in PT is required by ISO/IEC 17025 (5.9)

- EU RL VETC will be compliant with ISO/IEC 17043 within 2011
Background: ISO/IEC 17043


- ILAC G13 will be retired within two years from publication of ISO/IEC 17043.
Definitions – What is it?

Proficiency testing
Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

– Quantitative / qualitative scheme
– Single occasion exercise/ continuous scheme
– Sequential / simultaneous scheme
– Sampling
– Data transformation and interpretation
Definitions – Who’s involved?

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

- **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
Other Definitions – What is it?

- **proficiency testing round** - single complete sequence of distribution of proficiency test items, and the evaluation and reporting of results to the participants.

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

- Evaluation of the performance of laboratories
- Identification of problems
- Qualification of personnel
- Establishment of the comparability of test methods
- Provision of additional confidence to laboratory customers
- Identification of interlaboratory differences
- Education of participating laboratories based on the outcomes
Type of PT
Quantitative schemes

The objective is to quantify one or more measurands in the proficiency test item

- Results are numeric
- Tests for quantitative measurement may vary in their precision, trueness, analytical sensitivity, and specificity.
- Numeric results are usually analysed statistically.
Qualitative schemes

The objective is to identify or describe one or more characteristics of the proficiency test item

- The results are descriptive and reported on a categorical or ordinal scale (e.g., identity of micro-organisms, or by identification of the presence of a specific measurand (e.g. a drug or a grading of a characteristic).

- Assessment of performance by statistical analysis may not be appropriate
Sequential Scheme

One or more items are distributed sequentially and returned to the organizer at intervals

(sometimes known as measurement comparison schemes)
Simultaneous Scheme

The proficiency test items are distributed for concurrent testing within a defined time period

- The results are returned to the proficiency testing provider and compared with the assigned value(s) to give an indication of the performance of the individual participants and the group as a whole.
- Examples of proficiency test items used in this type of scheme include food, body fluids
Single occasion / Continuous schemes

- Single occasion exercises: proficiency test items are provided on a single occasion

- Continuous schemes: proficiency test items are provided at regular intervals
Let’s look at the ISO/IEC 17043 in more detail
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Annex A
Provides further explanation of definition of PT (Sequential schemes, Simultaneous schemes…)

Annex B
Provides further explanation on statistical methods for proficiency testing

Annex C
Selection and Use of Proficiency Testing
- Separate sections for laboratories and for “interested parties”
  - Accreditation bodies
  - Regulatory bodies
  - Participant Laboratories
ISO/IEC 17043: General Format

- Structure similar to ISO 17000 series
- Part 4: Technical requirements compliant with ISO/IEC 17025
- Part 5: Management requirements corresponding to ISO 9001 principles

✓ (Note: in contrast with ISO/IEC 17025, technical requirements come before management requirements)
Technical requirements

- Assure technical competence of PT providers

- Some of them are specific of this international standard e.g. Design of proficiency testing schemes, Operation of proficiency testing schemes, data analysis and report

- Other (e.g. personnel qualification, equipment management and maintenance) are compliant with ISO/IEC 17025 requirements
Key issues

Design of proficiency testing schemes

Report
Design of proficiency testing

Planning: Before starting PT scheme, the provider shall identify, plan and document those processes which directly affect the quality of the proficiency testing scheme.
Design of proficiency testing

- Preparation of proficiency test items:
  - requirements for the production, QC, storage and distribution of PT items

- Homogeneity and stability
  - procedures for homogeneity / stability testing /biological viability determination
  
- Statistical design
  - Developed to meet the goals of the scheme,
  - Covering process of planning, collection, analysis and reporting
  - Alternative approaches in case of insufficient number of participants
Reports

Highlights on the importance of the main product of proficiency testing

(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:

... 

✓ Data analysis for the whole group of participants and by groups of participants using the same procedure
✓ Comments on participants’ performance
✓ Comments or recommendations, based upon the outcomes of the proficiency testing round
Subcontracting not allowed for:

- Planning of PT schemes,
- Evaluating performance,
- Authorizing final reports
Management requirements

ISO 17043 require to providers of PT:

☑ To identify a “coordinator”: one or more individuals with responsibility for organizing and managing all of the activities involved in the operation of a proficiency testing scheme

☑ To establish an advisory group of experts (to assure the necessary technical expertise in the field of testing, calibration, statistics…..)

☑ To identify a quality manager
Conclusions

Implementation of ISO/IEC 17043:
- Warrants to customers (e.g. DG SANCO, National authorities) and end-users (e.g. accreditation bodies, consumers..) the reliability of PT results
- Warrants to participants an appropriate evaluation of their performances
- Promotes the educational scope of PT for laboratories
- Promotes harmonisation of PT practice
Thank you for your listening !!!
Laboratory management of the PT results

- Satisfactory result:
  - Independent proof of competence
  - Confirmation of method validation, qualification of personnel
  - Support to validation of new methods

- Unsatisfactory results: always cause analysis and corrective actions
- Annual review of all PT results
Definition of Strategy of participation: EA 4/18
Guidance on the level and frequency of PT

• Level an frequency according to criticism of areas of technical competence
• Selection of PT scheme:
• Relevance of scheme and provider competence
Data transformation and interpretation

- sets of data or other information are furnished and the information is processed to provide an interpretation (or other outcome) e.g. case study
EU RL VETEC  DGSANCO  NRL