International Standards for Proficiency Testing Providers

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This presentation was given at a workshop (June 2009 – Leuven Belgium) of the EuGeneTest, the EU-funded network of excellence for European genetics testing laboratories and PT providers.

The topic was to look at standards for quality and competence for proficiency testing providers.

The subject was the new creation of an ISO standard 17043, and where it would fit as a measure that EuGenTest providers could consider.
Proficiency Testing is Laboratory Quality
Proficiency Testing is a Quality Partner

- Proficiency Testing Providers
- Reagent Supplies Manufacturers
- Equipment Manufacturers
- Standards Development Bodies
- Accreditation Bodies
- Laboratorians

Laboratory Quality Management
All Quality Partners have Recognition Requirements

- Proficiency Testing Providers
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- Accreditation Bodies
- Equipment Manufacturers
- Reagent Supplies Manufacturers
- Laboratory Quality Management
- Laboratorians

ISO 17011
ISO 13485
ISO 15189
ISO 17011
ISO and Local Governance
Expectations of Quality Partners

Work within the Quality partnerships.

Quality partners should meet their Recognition Requirements.

Provide their product or service as required, on time, and on budget.
History of Proficiency Testing Provider Standards

There is no international organization, coalition, cooperation developed by and for proficiency testing providers.
EQALM

may be an exception

European Committee for External Quality Assurance Programmes in Laboratory Medicine

EQALM
Evolving into an international community
EUROPE
CANADA
ARGENTINA
JAPAN
ILAC
an assisting organization for PT providers

Created guidelines (Guides 13 and 43) for Accreditations Bodies to consider when selecting an PT provider to work with their programs.

Created the Proficiency Testing Consultation Group.

Worked with ISO to develop Quality Requirements for PT Providers
ISO 17043
Medical EQA providers

- ILAC G13 + ISO Guide 43: 7
- Accredited according to ISO 17020/ISO Guide 43: 4
- Accredited according to ISO 17025/ISO Guide 43: 4
- Accredited according to ISO 17025/ISO 17020/ISO Guide 43: 4
- ILAC G-13: 1
- Certified ISO 9000: 9
- CPA accredited: 2

TOTAL
31 Programs
We at CMPT are a university based, peer directed program, and strive to provide Innovative External Quality Assessment committed to education and continual improvement for the benefit of healthcare, our participants and our program.
Initiated in June 2007.

Currently just passed a successful DIS vote.

FDIS vote likely in September 2009
So Let’s Compare…
## ISO Guide 43-1:1997

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ISO 17043: 2010

Technical Requirements
- Personnel
- Equipment, Accommodation, and Environment
- Design
- Preparation of Materials
- Choice of Methods
- Operation of Program
- Data Analysis
- Reports
- Communications
- Confidentiality

Management Requirements
- Organization
- Management System
- Document Control
- Review of Requests, Tenders, Contracts
- Subcontracting Services
- Purchasing services and supplies
- Service to the customer
- Complaints
- Control of nonconforming activities
- Improvement
- Corrective Actions
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The staff involved in providing the scheme should have, or collaborate closely with those holding adequate qualifications and experience in the design, implementation and reporting of interlaboratory comparisons. They should include appropriate technical, statistical and administrative skills.

The operation of particular interlaboratory comparisons will also require the guidance of persons with detailed technical knowledge and experience of the test methods and procedures involved. To this end the coordinator may need to enlist one or more appropriate persons drawn from, for example, professional bodies, a contract laboratory (if any), scheme participants or end users of the data, to act as an advisory group.
Technical Requirements
Personnel 17043:2010

• Personnel
  – Management shall define qualifications
  – Management shall provide and monitor education and training as required.
  – Management shall monitor competency.

• Personnel shall be authorized to perform the following tasks:
  – Selecting materials
  – Planning challenges
  – Performing sampling
  – Operating equipment
  – Conducting measurements
  – Preparing, handling, and distributing items
  – Conducting statistical analysis.
  – Evaluating performance
  – Creating and distributing reports
  – Providing opinion and interpretation
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5.2.3 The functions of this advisory group may include:

- the development and review of procedures for the planning, execution, analysis, reporting and effectiveness of the proficiency testing scheme;

- the identification and evaluation of inter-laboratory comparisons organized by other bodies;

- the evaluation of proficiency test results regarding the performance of participating laboratories;

- providing advice to any body assessing the technical competence of participating laboratories,

- providing advice to participants apparently experiencing problems; and

- resolving any disputes between the coordinator and participants.
Advisory Committee duties

17043

planning requirements;

identification and resolution of any difficulties expected in the preparation and maintenance of homogeneous proficiency test items or in the provision of a stable assigned value for a proficiency test item;

preparation of detailed instructions for participants;

comments on any technical difficulties or other remarks raised by participants in previous proficiency testing rounds;

provision of advice in evaluating the performance of participants;

comments on the results and performance of participants as a whole and, where appropriate, groups of participants or individual participants;

provision of advice for participants (within limits of confidentiality), either individually or within the report;

responding to feedback from participants; and planning or participating in technical meetings with participants.
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responding to feedback from participants; and planning or participating in technical meetings with participants.
Detailed instructions covering all aspects of the scheme which should be adhered to by the participating laboratories should be provided. These may be provided, for example, as an integral part of a scheme protocol.

Instructions may include details concerning factors which could influence the testing of the supplied test items or materials. Such factors may include operators, the nature of items or materials, equipment status, selection of test procedure and timing of testing.

Specific instructions on the recording and reporting of test or calibration results may also be supplied (e.g. units, number of significant figures, reporting basis, result deadlines, etc.).

Participants should be advised to treat proficiency test items as if they were performing routine tests (unless there are some special requirements in the design of the proficiency test which may require departure from this principle).
Detailed documented instructions

Instructions to participants shall include:

a) factors which could influence the testing or calibration
b) procedure for preparing test items
c) instructions on handling the proficiency test items, including safety
d) specific environmental conditions for tests and/or calibrations
e) instructions on the manner of recording and reporting results
f) the necessity to treat proficiency test items in the same manner as the majority of routinely tested samples
g) the latest date for the provider to receive results
h) instructions on return of the proficiency test items.
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Instructions for participants

4.6.1.1

The proficiency testing provider shall give participants sufficient prior notice before sending proficiency test items, providing the date upon which the proficiency test items are likely to arrive or to be dispatched, unless the design of the proficiency testing scheme makes it inappropriate to do so.
4.7.2.1

The PT/EQA provider shall use valid methods of evaluation which meet the purpose of the PT/EQA scheme.

The methods shall be documented and include a description of the basis for the evaluation.

The evaluation of performance shall not be subcontracted.
4.7.2.2
Where appropriate for the purpose of the PT/EQA scheme, the provider shall provide expert commentary on the performance of participants with regard to the following:

a) overall performance
b) variation within and between participants
c) comparisons with previous PT/EQA rounds, similar or published precision data;
d) variation between methods or procedures;
Commentary on Performance
continued

e) possible sources of error and suggestions for improving performance;
f) advice and educational feedback to participants

g) situations where factors make evaluation of results impossible;

g) any other suggestions, recommendations or general comments; and

h) conclusions.
PT and Uncertainty

Some areas need discussion

Addresses Measurement Uncertainty as a statistical issue only as it applies to calculation of assigned values and stability.

Does not address the estimation of factors that can have an impact on sample uncertainty.

Also does not demonstrate the benefits of calculating measurement uncertainty.
Why ISO 17043 provides so much flexibility in its requirements.
Why ISO 17043 provides so much flexibility in its requirements.

Medical

Food  Water  Veterinary  Industrial  Environmental  Electrical  PT EQA
Challenges for ISO17043

• Application
  – Is it better than Guide 43-1?
  – Where does it fit with ISO9001:2008?

• Cost

• Confidence in Assessment Process.
  – Knowledge and Interpretation
  – Bias
  – Competence
Challenges for ISO17043

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- **Cost**
  - (?)

- **Confidence in Assessment Process.**
  - Knowledge and Interpretation
  - Bias
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Strategy for Going Forward

- Purchase ISO 17043

- IMPLEMENT ISO 17043

- ACCREDITATION TO ISO 17043
- NO ACCREDITATION TO ISO 17043

- CHOICES

- ACCREDITATION ISO17025 or ILAC G13
- CERTIFICATION ISO 9001
Accreditation or Not Accreditation

Reasons for Accreditation
- External Validation
- Demonstration Value
- Business Opportunities
- Public Relations

Reasons for Not Accreditation
- Availability
- Cost
- Business Realities
- Accreditation Body Competence.
Do Laboratories Care?

- **Some might**.
  - Local factors are very important
    - Government authority
    - Accreditation bodies
    - Laboratory personal factors
      » How well are the laboratarians informed and knowledgeable about quality?
      » “If we have to, you have to.”
Alternatives to Accreditation

Depends on the Reason

For External Validation or External Audit
- International committee of peers
- Quality Consultant Group
- National accreditation body for unofficial visit

For Accreditation or Certification Certificate
- NONE
To sum up ISO17043:2010?

- Not a big jump from existing documents
  - ISO 17043 is better organized
  - More current
  - More relevant
  - Lots of good practice
  - Lots of flexibility
  - Addresses measurement uncertainty narrowly.

- A document that I can work with at CMPT
in summary...

- Proficiency Testing Providers are a valuable Quality Partner for medical laboratories.
- Proficiency Testing Providers will soon have their own ISO standard for quality assessment (ISO 17043).
- Working to meet Quality Assessment requirements should be a goal for all Proficiency Testing Providers.
- The decision to seek accreditation is different from the decision to meet quality requirements.
and finally final.

- Whether or not you decide to consider accreditation, you should **follow the recommendations** in ISO17043 because...