It is time to review and revise ISO/IEC 17043:2010 ?

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Note1:

The opinions being presented are MY opinions.

You may or may not agree with them.

My intend is NOT to convince you that I am right,
but rather
to open up the EQALM conversation
on the current status and suitability of
our international standard
for general requirements of a
medical laboratory
EQA scheme.

35 years of history behind IS0/IEC 17043

- In **1984** ISO and IEC published ISO/IEC Guide 43 (*Development and operation of laboratory proficiency testing*)
- In **1997** the document was updated IEC Guides43-1 and 43-2. (*Proficiency testing by interlaboratory comparisons*)
- In **2000** International Laboratory Accreditation Cooperation (ILAC) ISO adopted and adapted ILAC G13 (*Guidelines for the Requirement for the Competence of Providers of Proficiency Testing Schemes*)
- In **2005** at the request of ILAC Proficiency Testing Committee, ISO CASCO began the work on raising Guide 43 to the level of an international standard.
- In **2010**, ISO/IEC 17043:2010 (*Conformity assessment – general requirements for proficiency testing*) was published.

Current status of ISO/IEC 17043:2010

Eight years after publication the standard remains unreviewed* and unrevised.**

This is inconsistent with ISO Secretariat Rules

Which require a review every 5 years.

*ISO CASCO may have done an internal review, but there has not been a stakeholders' review

** There was an internal published revision to ISO13528 (**Statistical methods for use in proficiency testing by interlaboratory comparisons)**

In my opinion…

We (EQALM) as the largest international and intercontinental organization committed to PT/EQA for the medical laboratory community have an **right and expectation and an obligation** to:

1. Create a committee of interested parties
2. Review the standard
3. Draft a report
4. Share the report with ISO CASCO
5. Insist that a formal review of the standard is undertaken, and our report is taken into consideration.
6. Apply for and insist on formal Liaison status with ISO CASCO for all future changes in ISO/IEC17043.

But even though nobody has asked, let me share ***my*** thoughts about this standard as applied to medical laboratory EQA

- First …
  I understand that ISO/IEC 17043 is intentionally NOT sector specific.
  and
  I *do not think* that we are sufficiently different from Proficiency Testing programs in other sectors that would require a separate sector specific standard for EQA for medical laboratories.

Laboratories with identical PT/EQA needs as medical laboratories

- Water testing
- Food testing
- Drug testing
- Veterinary laboratories
- Cannabis testing laboratories

- Multiple laboratory disciplines
  - Chemical
  - Microbiological
  - Target specific
- Varied testing techniques
  - Classical Quantitative/Qualitative
  - Microscopic
  - Immunodiagnotic
  - Molecular
- Multiple laboratory phases
  - Pre-Examination
  - Examination
  - Post-Examination
  - Peri-Examination

Following a “thorough and thoughtful (?)” personal review of ISO/IEC 17043:2010, I came to following conclusions…

1. Most of the document holds up and does NOT need revision.
2. There are parts of the standard that were way ahead of other laboratory standards, which are only now starting to catch up.
    2. Service to the Customer
    3. Causal Analysis
3. There are parts of the standard that I think should be revised.

Service to the customer

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ISO/IEC is more focused on “customer service” than either ISO9001:2015 or ISO 15189:2012 or ISO/IEC17025:2017

The proficiency testing provider ***shall be willing to cooperate with participants*** and other customers in clarifying customers' requests and in monitoring the proficiency testing provider's performance in relation to the work performed, provided that the proficiency testing provider assures confidentiality to its participants.

The proficiency testing provider ***shall seek feedback, both positive and negative***, from its customers. The feedback shall be used and analysed to improve the management system, proficiency testing schemes, and customer service.

The proficiency testing provider shall have a policy and follow a procedure for ***the resolution of complaints and appeals received*** from participants, customers or other parties.

Places where I think
ISO 17043
should be
REVISED

4.4.1.3 Planning a “new scheme”

The proficiency testing provider shall document a plan before commencement of the proficiency testing scheme that addresses the objectives, purpose and basic design of the proficiency testing scheme, including the following information and, where appropriate, reasons for its selection or exclusion:

Name and Address of the PT Provider
Name and Address and Affiliation of the Coordinator and other personnel
Criteria to be met for participation.
Number and type of expected participants.
Reasonable precautions to prevent collusion between participants or falsification of results, and procedures to be employed if collusion or falsification of results is suspected
A detailed description of the statistical analysis to be used;
The origin, metrological traceability and measurement uncertainty of any assigned values;
Criteria for the evaluation of performance of participants
A description of the extent to which participant results, and the conclusions that will be based on the outcome of the proficiency testing scheme, are to be made public

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This section needs TWO revisions including
ONE Deletion
and ONE Addition

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It is NOT the responsibility or authority of
EQA providers to prevent participant collusion.
That is the task of
Laboratory Accreditation Bodies
Laboratory Licencing Bodies
Authorized (Governmental) Oversight Bodies

EQA may have some responsibility to REPORT evidence
of known or highly probable
of intermember collusion

4.4.1.5

Technical expertise shall be use
matters such as the followin

a) planning requirements as listed in 4.
b) preparation of detailed instructions
c) comments on any technical difficulti
proficiency testing rounds;
d) provision of advice in evaluating the p
e) comments on the results and performa
appropriate, groups of participants or ind
f) provision of advice for participants (within li
within the report;
g) responding to feedback from participants; and
h) planning or participating in technical meetings with participants.
i) 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;

Recommend addition:
Insert after (c)

Technical expertise SHALL ensure that the selection and timing and complexity of samples is appropriate to the laboratories receiving the samples

EQA Providers must accommodate customer needs

There are 16 references with in the document to “interlaboratory comparisons”

The Introduction starts…
“Interlaboratory comparisons are widely used for a number of purposes and their use is increasing internationally. Typical purposes for interlaboratory comparisons include:”

Places where I think that ISO 17043: 2010 should be improved.

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It is time to retire
the archaic term
"Interlaboratory Comparison"

What is a *comparison*

- Examination of two or more items to establish similarities and dissimilarities
- Denoting different levels of quality, quantity, or relation
- ***To classify or categorize one versus another.***

We do NOT compare one laboratory performance. We MEASURE competence .

- We usually measure laboratory performance against a known objective standard or expected target.
- We do NOT measure performance by pitting one laboratory against another.

What is a *comparison?*

When we have a class of students and we give them a Quiz,
we DO NOT CALL it an “Interstudent Comparison”

When a person is being tested for their Driver’s Licence
We don’t call that an
“Interdriver Comparison”

We call them <u>assessments</u> <u>of</u> <u>performance</u>.

A Comparison is what they do at Beauty Contests

Annex A.4 should be revised

- Many EQA programmes are designed to provide insight into the complete path of workflow of the laboratory, and not just the testing processes.
- ***A typical feature of EQA programmes is to provide education to participants and promote quality improvement. Advisory and educational comments comprise part of the report returned to participants to achieve this aim.***
- ***Some EQA programmes assess performance of pre-analytical and post-analytical phases of testing, as well as the analytical phase.***
- Alternatively, pre-analytical information may accompany the proficiency test item, requiring the participant to select an appropriate approach to testing or interpretation of results, and not just to perform the test.

Annex A.4 should be revised

- Many EQA pr… …sight into the complete… …just the testing proces…
- ***A tw… …on to po… …d e… …to p…***
- ***S… …and po… …ase.***
- Alte… …e profici… …n appropri… …sults, and not just to perfo…

Promotion of Continual Improvement by provision of educational, advisory or informative information should be a **NORMATIVE REQUIREMENT**.

Extension of EQA to include Pre-Examination and Examination and Post-Examination phases should be a **NORMATIVE REQUIREMENT**

In summary …

- Many EQA providers have benefited through the application of ISO/IEC 17043:2010
- In **MY** opinion the document has “opportunities for improvement”.

- Regardless,
  EQALM as the largest (?) international, intercontinental organization committed to EQA performance and improvement, should be *actively* involved in any and all review and revision of standard.

And …

We (EQALM) as an international organization committed to PT/EQA for the medical laboratory community have an **obligation** to:

1. Create a committee of interested parties
2. Review the standard
3. Draft a report
4. Share the report with ISO CASCO
5. And if necessary insist that a formal review of the standard is undertaken, and our report is taken into consideration.
6. REQUEST formal Liaison status with ISO CASCO