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The role of accreditation bodies and EQA organisers in the assessment of analytical quality specifications

Ian Mann
Swiss Accreditation Service
ian.mann@sas.ch

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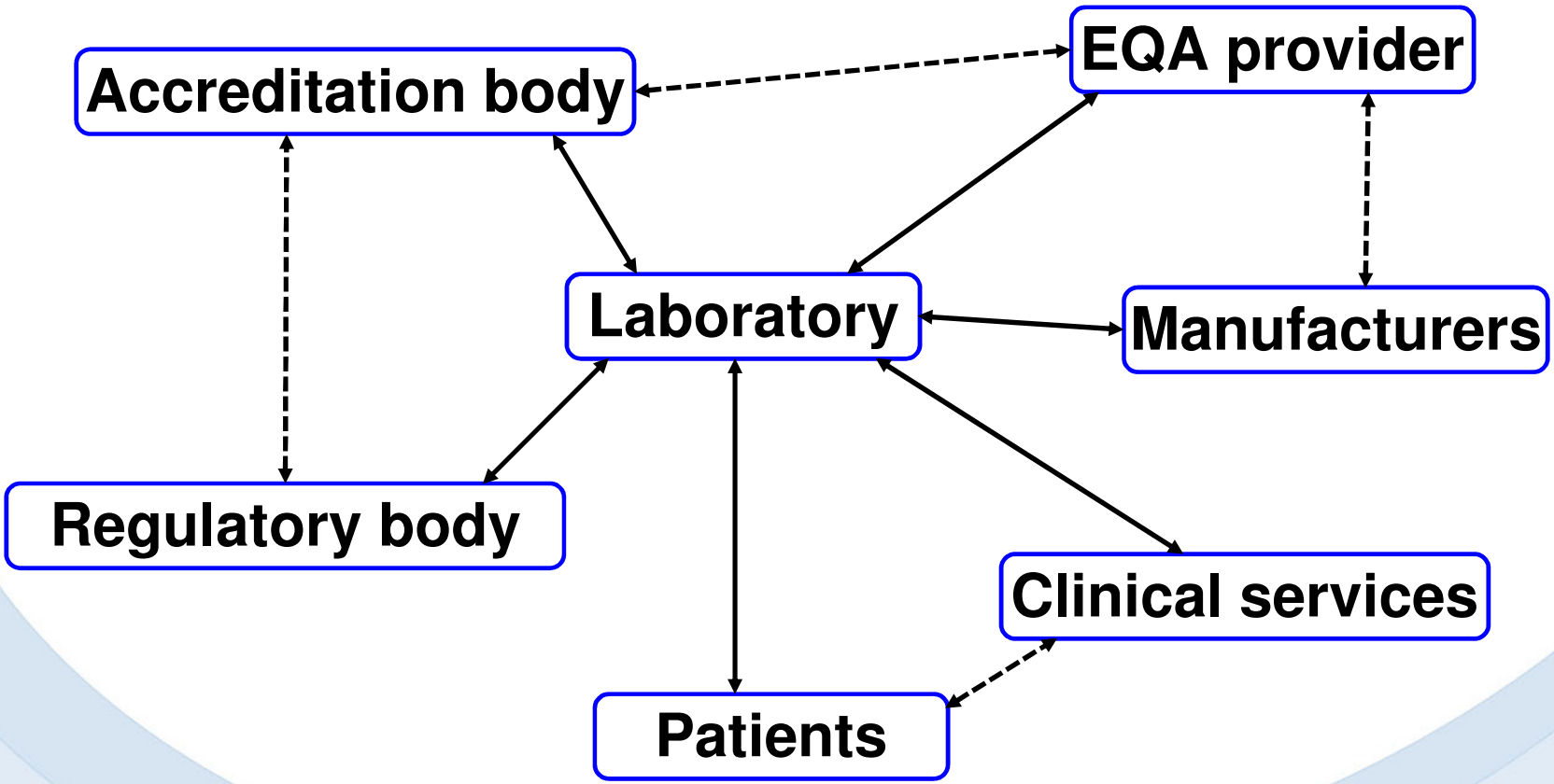
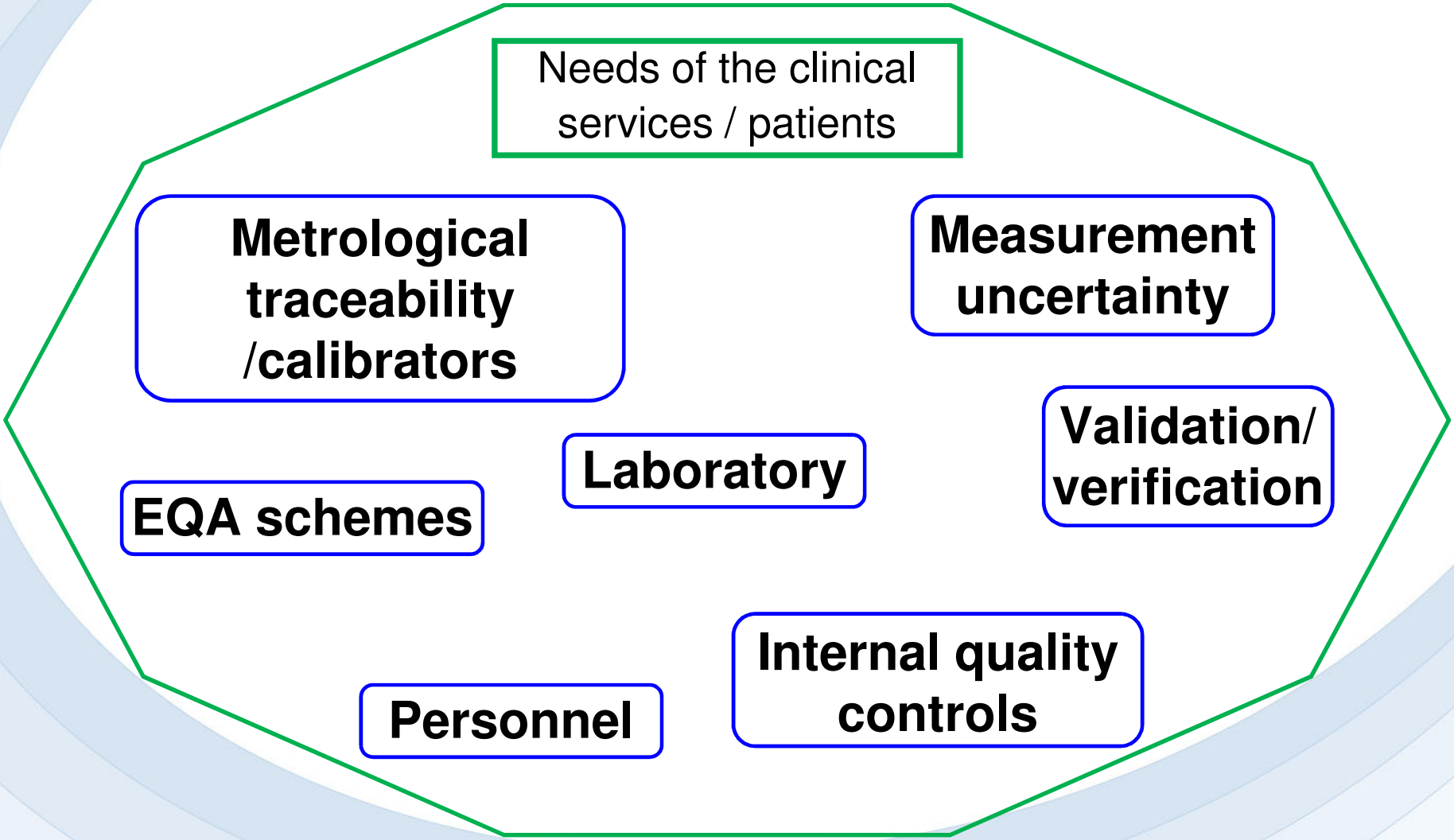
"Partners" of the laboratory



Assessment of analytical performance



Assessment requirements

ISO 15189: 2007

"Medical laboratories — Particular requirements for quality and competence"

ISO/IEC 17025 : 2005

"General requirements for the competence of testing and calibration laboratories"

ISO /IEC 17011 : 2004

"Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies"

Assessment requirements

ISO 15189: 4.7 Advisory services

Appropriate laboratory professional staff shall provide advice on choice of examinations and use of the services, including repeat frequency and required type of sample. Where appropriate, interpretation of the results of examinations shall be provided.

There should be regular documented meetings of professional staff with the clinical staff regarding the use of the laboratory services and for the purpose of consultation on scientific matters. The professional staff should participate in clinical rounds, enabling advice on effectiveness in general as well as in individual cases.

Assessment of a laboratory

If the assessment is focused on:

- Are the records signed and dated?
- Can you retrieve last year's results?
- Are the records stored confidentially?
- Is the continuous training recorded?
- Are the non-conformities signed by the quality or technical manager?
- Do you have regular internal meetings?
- Do you plot your internal quality controls?
- With whom are the EQA results discussed?

The performance of the laboratory will not be correctly assessed.

Assessment of a laboratory

The assessment should focus on:

- Are the internal quality controls appropriate (quantity, level, similar to real samples)?
- Is the personnel trained on clinical aspects?
- When relevant, how is the measurement uncertainty used when interpreting the results ?
- Has the validation/verification taken into account the purpose of the analysis?
- When relevant, are the results metrologically traceable?
- Is the level and frequency of participation in EQA schemes appropriate?

Benefits of participation in EQA schemes

- Identifying Testing or Measurement Problems (as a risk management and performance improvement tool)
- Comparing Methods or Procedures
- Improving Performance
- Educating Staff
- Instilling Confidence in Staff, Management, and External Users of Laboratory Services
- Determining Method Precision and Accuracy
- Exchange of information with the PT provider
- Measurement Uncertainty

Ref.: Benefits for Laboratories participating in Proficiency Testing Programs (ILAC brochure, 2008 / www.ilac.org)

Accreditation requirements for AB's

ISO /IEC 17011 : 2004: Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

"7.15 Proficiency testing and other comparisons for laboratories

7.15.1 The accreditation body shall establish procedures to take into account, during the assessment and the decision-making process, the laboratory's participation and performance in proficiency testing."

Accreditation requirements for AB's

ISO /IEC 17011 : 2004:

"7.15.2 The accreditation body may organize proficiency testing or other comparisons itself, or may involve another body judged to be competent. The accreditation body shall maintain a list of appropriate proficiency testing and other comparison programmes.

Note : Guidelines on operation and selection of proficiency testing and related definitions exist in ISO/IEC Guide 43-1 and ISO/IEC Guide 43-2."

Accreditation requirements for AB's

ISO /IEC 17011 : 2004:

"7.15.3 The accreditation body shall ensure that its accredited laboratories participate in proficiency testing or other comparison programs, where available and appropriate, and that corrective actions are carried out when necessary. The minimum amount of proficiency testing and the frequency of participation shall be specified in cooperation with interested parties and shall be appropriate in relation to other surveillance activities.

Note 1: It is recognized that there are particular areas where proficiency testing is impractical.

Note 2 : Proficiency testing may also be used in many types of inspection. Clause 7.15 should be read in this sense."

Level and frequency of participation in EQA

- Draft position paper from the EEE-PT working group (EA-Eurachem-Eurolab/ EQALM is an affiliated member).
- Promote harmonisation between accreditation bodies on how the level and frequency of participation in PT/EQA is evaluated.
- Assist laboratories in determining their own levels and frequency of participation, taking into consideration the other quality measures.
- Level : Number of specific scheme's in which a laboratory participates.
- Frequency : How often a laboratory participates in a specific scheme.

Level and frequency of participation in EQA

- A number of factors should be considered by the laboratories when establishing the level and frequency of participation.

  Other quality control measures:
  - Use of CRM/RM/Calibrators
  - Comparison of analysis by independent techniques
  - Use of internal quality controls
  - Interlaboratory comparisons (between a small number of laboratories).

Level and frequency of participation in EQA

The level of risk

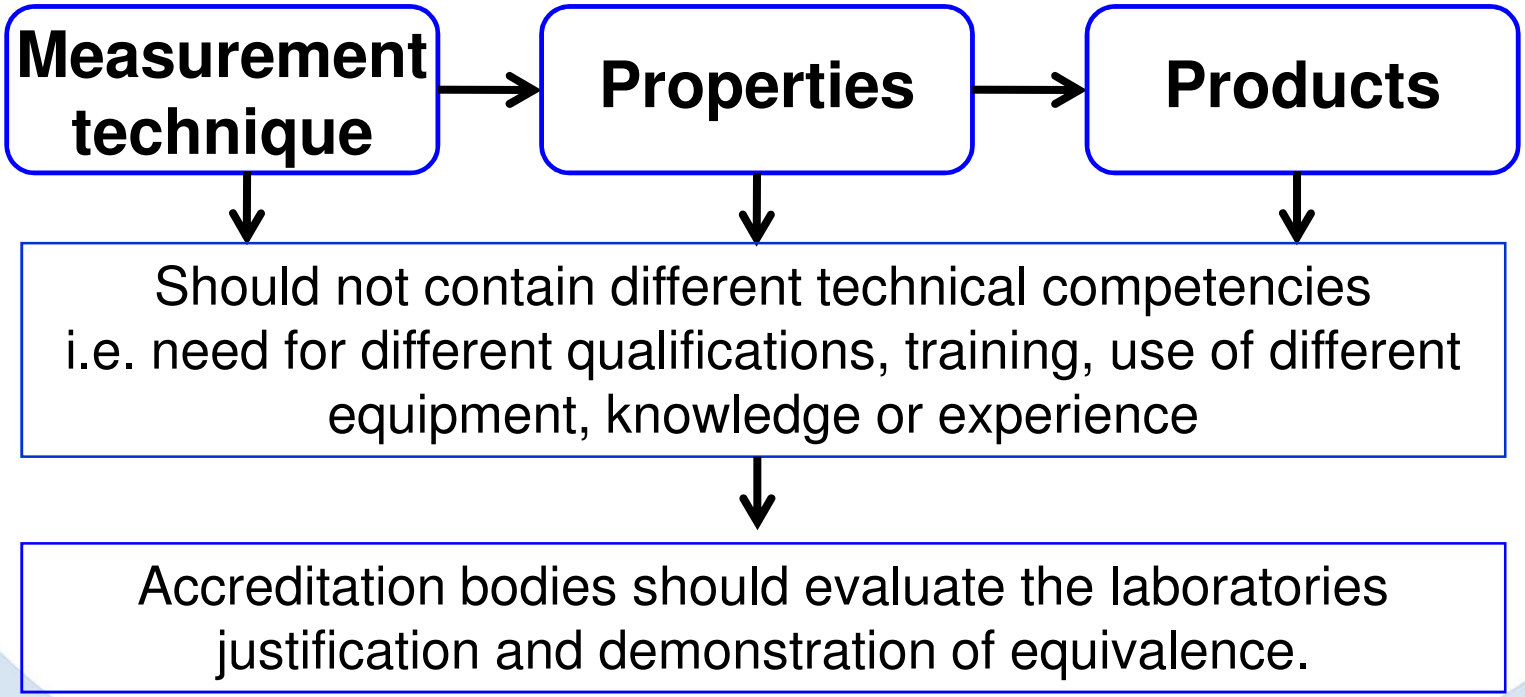
- Number of tests undertaken
- Turnover of technical staff
- Experience and knowledge of technical staff
- Known stability/instability of the analysis
- Clinical significance and final use of the results.

Areas of competence

- EA highly recommends EQA participation in each “sub-discipline” or “area of technical competence”.
- Laboratories need to identify their areas of technical competence.
- Not logistically or economically possible for a laboratory to participate in every EQA scheme available.
- EQA schemes are not available for all analysis.
- Accreditation bodies expect laboratories to identify groups of sets of measurement techniques, properties and products.

Areas of competence

It is useful to consider a stepwise approach:



Level and frequency of participation in EQA

- For each area of technical competence, in conjunction with the other quality measures, a laboratory should set a strategy of participation in EQA schemes.
- Strategy should cover a specific period (accreditation cycle) and be updated every year.
- Accreditations bodies should evaluate the suitability of the laboratory's strategy.

Role of EQA provider

- Play a very important role in the assessment of competence.
- EQA provider should operate according to recognized requirements (ISO/IEC 17043).
- EQA provider should be able to respond to the needs of the laboratory taking into account the area of competence approach.
- Collaboration between laboratories – EQA providers- Accreditation bodies to fill in the necessary gaps.

Role of Accreditation Bodies

Thank you for your attention!

Questions?