# Why traceability is important to EQA providers.

**On behalf of the EQALM**
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# EQALM

**European Organisation for External Quality Assurance Providers in Laboratory Medicine.**

# SCOPE

**EQALM, European Organisation for External Quality Assurance Providers in Laboratory Medicine, provides a forum for co-operation and exchange of knowledge on quality-related matters especially with regard to external quality assessment / assurance programmes in Europe.**

# External Quality Assessment/Assurance:

**3.7**
**proficiency testing**
evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

NOTE 2 Some providers of proficiency testing in the medical area use the term "External Quality Assessment (EQA)" for their proficiency testing schemes, or for their broader programmes, or both (see Annex A). The requirements of this International Standard cover only those EQA activities that meet the definition of proficiency testing.

INTERNATIONAL STANDARD **ISO/IEC 17043**

## A.4 External quality assessment (EQA) programmes

EQA programmes (such as those provided for laboratory medicine examinations) offer a variety of interlaboratory comparison schemes based on this traditional proficiency testing model, but with broader application of the schemes described in A.2 and A.3 and illustrated in Figure A.1. Many EQA programmes are designed to provide insight into the complete path of workflow of the laboratory, and not just the testing processes. Most EQA programmes are continuous schemes that include long term follow-up of laboratory performance. 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.

INTERNATIONAL STANDARD **ISO/IEC 17043**

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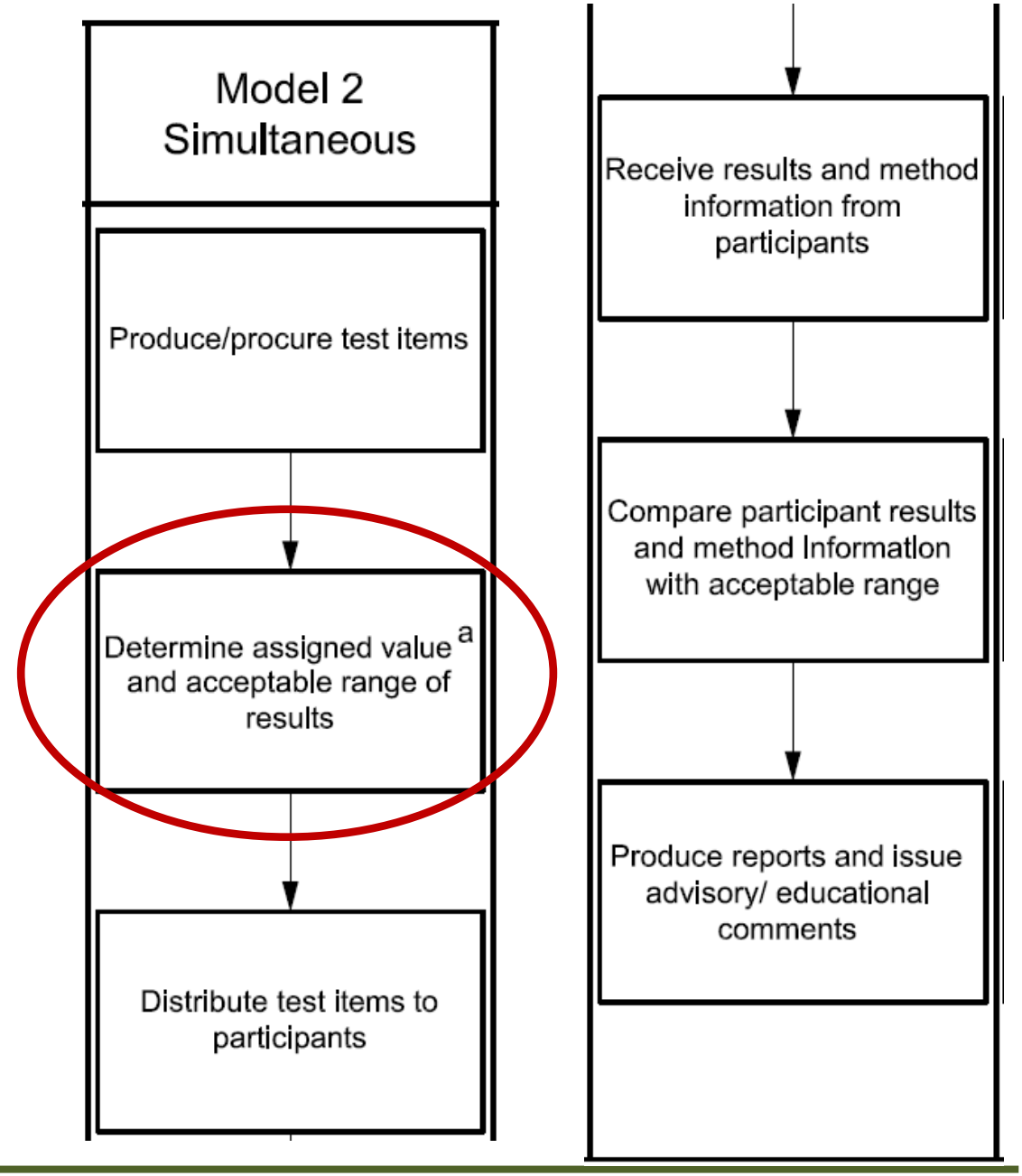


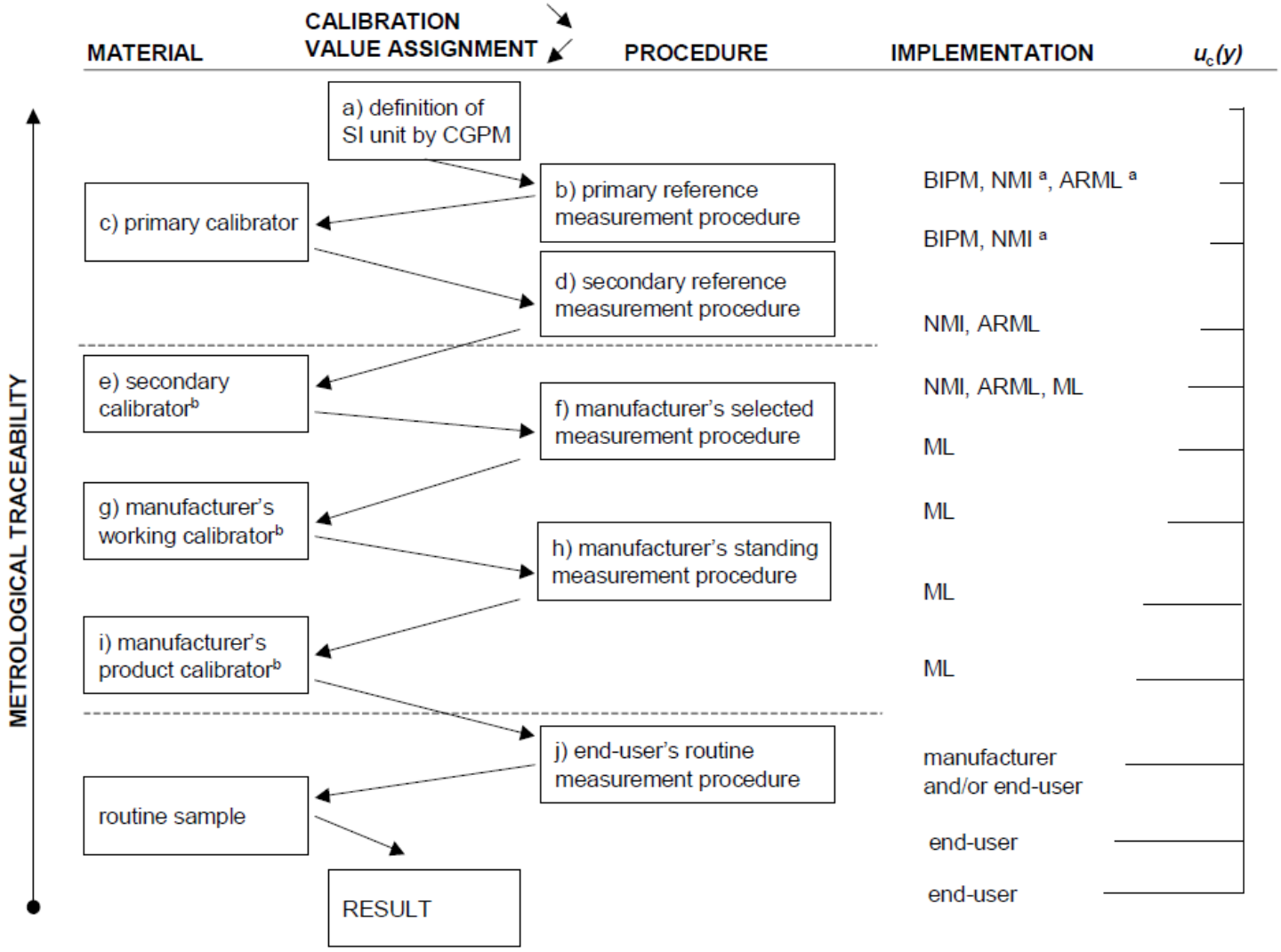
# Value assignment in EQA:

A. Value assignment by Certified Reference Material
B. Results from reference laboratory
C. Consensus value from expert laboratories
D. Consensus value from participants results

INTERNATIONAL STANDARD **ISO 13528**

**A / B**

**C / D**




INTERNATIONAL STANDARD **ISO 17511**

# EQALM QUESTIONNAIRE ON TRACEABILITY (2016)

**Aim**:

To Investigation the implementation of the use of value assignment with CRM or RMP's in EQA programmes.

**QUESTIONNAIRE ON TRACEABILITY**

**GENERAL INFORMATION**

| | |
|---|---|
| Name EQA organisation | |
| Country | |
| Specify the total number of measurands in the schemes of your EQA organisation (includes all different disciplines like clinical chemistry, immunology, haematology etc). | |
| Specify the total number of measurands with target values traceable to primary standard | |

**SPECIFIC INFORMATION FOR MEASURANDS WITH REFERENCE METHOD TARGET VALUES**

Please, complete the table below for each measurand with traceable target values

| Measurand | Primary Standard | Reference Method | Value Assigment | No. of Reference Laboratories | Accreditation Reference Laboratories | No. of surveys with reference method target values per year | No. of participants | Do you have also for this measurand surveys without reference method target values | No. of surveys without reference method target values per year | Accreditation EQA programme for this measurand | Comments |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 1=EQA organisation<br>2=Reference laboratory<br>3=both | If reference laboratories are used for value assigment, how many labs are used? | How many of the reference laboratories are accredited and which standard? | | | (Yes/No) | | (Yes/No) | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |

# EQALM QUESTIONNAIRE ON TRACEABILITY (2016)

| | |
|---|---|
| No. of EQA organisations: | 58 |
| No. of responders: | 14 (= 24%) |
| No. of responders without CRM / RMP: | 6 |
| No. of responders with CRM / RMP: | 8 (= 14%) |

# EQALM QUESTIONNAIRE ON TRACEABILITY (2016)

| | |
|---|---|
| No. of responders with CRM / RMP: | 8 |
| Total no. of measurands: | 47 – 1500 |
| No. of measurands with CRM / RMP: | 2 – 38 |
| Percentage measurands with CRM / RMP : | 1% - 13% |

| Measurand | Primary Standard | Reference Method | Value Assigment 1=EQA 2=Ref Lab 3=both | No. of Reference Laboratories | Accreditation Reference Laboratories | No. of surveys with | No. of participants per year | No. of surveys without | Accredited programme |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| Aldosterone | A6628, Sigma | ID-LCMSMS | 3 | 1 | ISO 17025, ISO 15195 | 4 | 7000 | | YES |
| Cortisol | SRM 921, NIST | ID-GC-MS | 3 | 1 | ISO 17025, ISO 15195 | 4 | 7000 | 2 | YES |
| Estradiol 17ß | CRM 6004-a, NMIJ | ID-GC-MS | 3 | 1 | ISO 17025, ISO 15195 | 4 | 7000 | | YES |
| Estriol | 24609, Merck | ID-GC-MS | 3 | 1 | ISO 17025, ISO 15195 | 4 | 7000 | | YES |
| Testosterone | CRM M914, NMIA | ID-GC-MS | 3 | 1 | ISO 17025, ISO 15195 | 4 | 7000 | | YES |
| Progesterone | CRM 6003-a, NMIJ | ID-GC-MS | 3 | 1 | ISO 17025, ISO 15195 | 4 | 7000 | | YES |
| 17 OH Progesterone | 3709, Merck | ID-LCMSMS | 3 | 1 | ISO 17025, ISO 15195 | 4 | 7000 | 6 | YES |
| Thyroxin, total | IRMM-468 | ID-LCMSMS | 3 | 1 | ISO 17025, ISO 15195 | 4 | 7000 | | YES |
| Triiodothyronine, total | IRMM-469 | ID-LCMSMS | 3 | 1 | ISO 17025, ISO 15195 | 4 | 7000 | | YES |
| Creatinine | SRM 914, NIST | ID-LCMS | 3 | 1 | ISO 17025, ISO 15195 | 12 | 9600 | 4 | YES |
| Cholesterol, total | SRM 911, NIST | ID-GC-MS | 3 | 1 | ISO 17025, ISO 15195 | 12 | 8600 | 4 | YES |
| Trigyceride, total | SRM 1595, NIST | ID-GC-MS | 3 | 1 | ISO 17025, ISO 15195 | 12 | 8600 | 4 | YES |

## Electrolytes

| Measurand | Number | CRM | RMP |
|---|---|---|---|
| Sodium | 4 | SRM 919b, NIST | ICP-OES<br>ICP-MS<br>Flame atomic emmision |
| Potassium | 4 | SRM 918b, NIST | ICP-OES<br>ICP-IDMS<br>Flame atomic emmision |
| Calcium | 4 | SRM 915, NIST | ICP-OES<br>ICP-IDMS<br>Flame atomic emmision |
| Lithium | 4 | SRM 924a, NIST | ICP-OES<br>ICP-IDMS<br>Flame atomic emmision |
| Magnesium | 4 | SRM 929, NIST | ICP-OES<br>ICP-IDMS<br>Flame atomic emmision |
| Chloride | 3 | SRM 919b, NIST | Coulormetric titration<br>ICP-IDMS |

# QUESTIONNAIRE ON TRACEABILITY

| Measurands |
|---|
| Serum - 17-OH-progesterone |
| Serum - Aldosterone |
| Serum - ALP |
| Serum - ALT |
| Serum - Amylase |
| Serum - AST |
| Serum - Bilirubin total |
| Serum - Bile acids total |
| Serum - Calcium |
| Serum - Chloride |
| Serum - Cholesterol |
| Serum - CK |
| Serum - Cortisol |
| Serum - Creatinine |
| Serum - CRP |
| Serum - Digoxin |
| Serum - Digitoxin |
| Serum - Estradiol |
| Serum - Estriol |
| Serum - GGT |
| Serum - Glucose |
| Serum - Glycerides total |
| Serum - HDL Cholesterol |

| Measurands |
|---|
| Serum - LDH |
| Serum - Lithium |
| Serum - Magnesium |
| Serum - Phoshate inorganic |
| Serum - Potassium |
| Serum - Progesterone |
| Serum - 17-OH-progesterone |
| Serum - Protein total |
| Serum - Sodium |
| Serum - Testosterone |
| Serum - Theophylin |
| Serum - Triglycerides |
| Serum - tT3 |
| Serum - tT4 |
| Serum - Urea |
| Serum - Uric acid |
| Urine - Creatinine |
| Blood - Hemoglobin A1c |
| Blood - Hemoglobin total |
| Blood - Erythrocytes |
| Blood - Leucocytes |

# Conclusions from questionnaire

1) Not all EQA organisers use samples with CRM/RMP assigned target values.

- No CRM/RMP available?
- Costs?
- Organisational limitations?

2) A maximum of 13% of the measurands included in an EQA programme is covered by the use of samples with CRM/RMP assigened target values.

- Does the smaller portion reflects to largest portion of clinical test?
- Are we limited by the fact no CRM/RMP for the measurand is available?

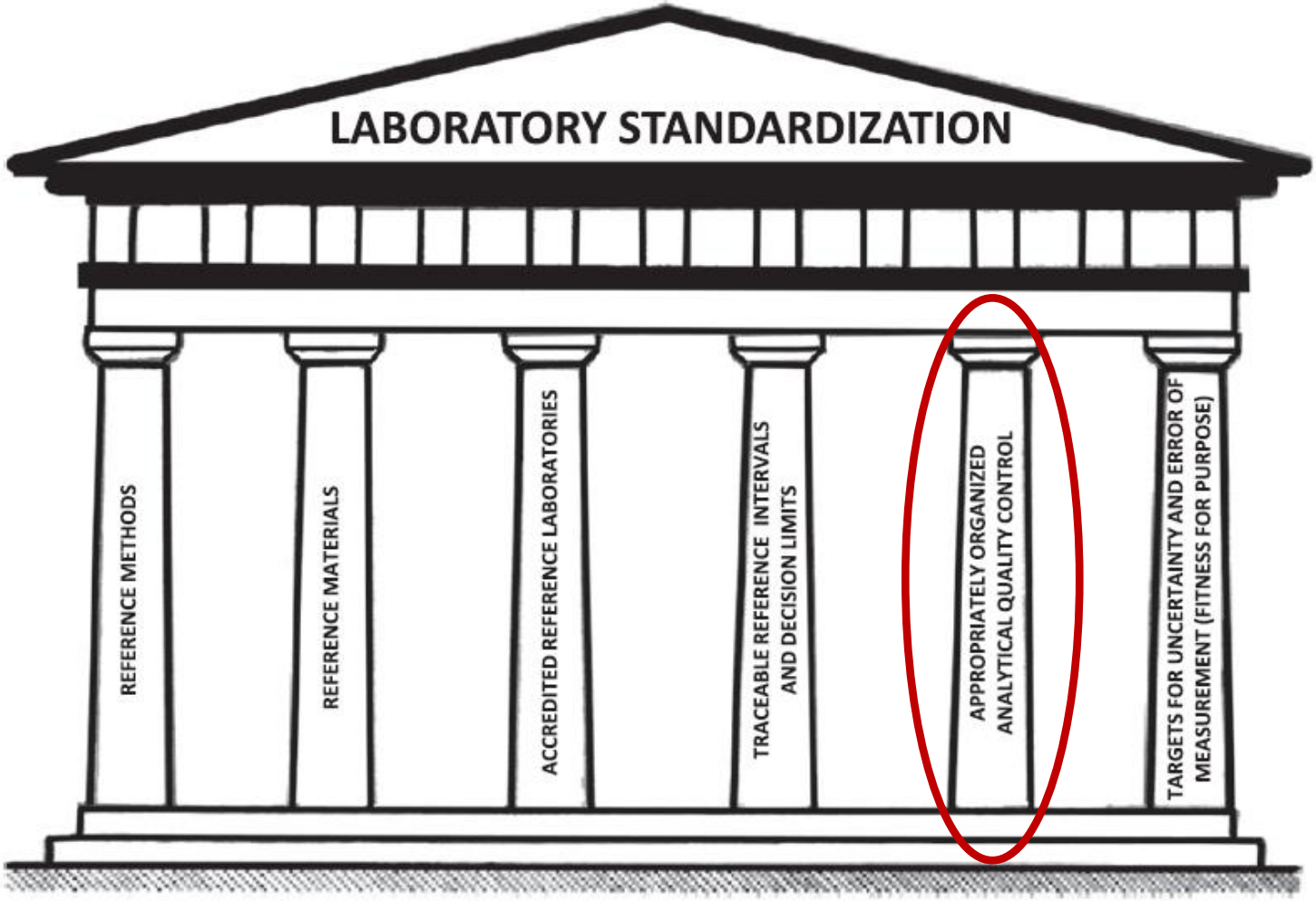



**Fig. 1.** The temple of laboratory standardization and its six pillars.

Braga *et al (2014), CCA; 432: 55 - 61*

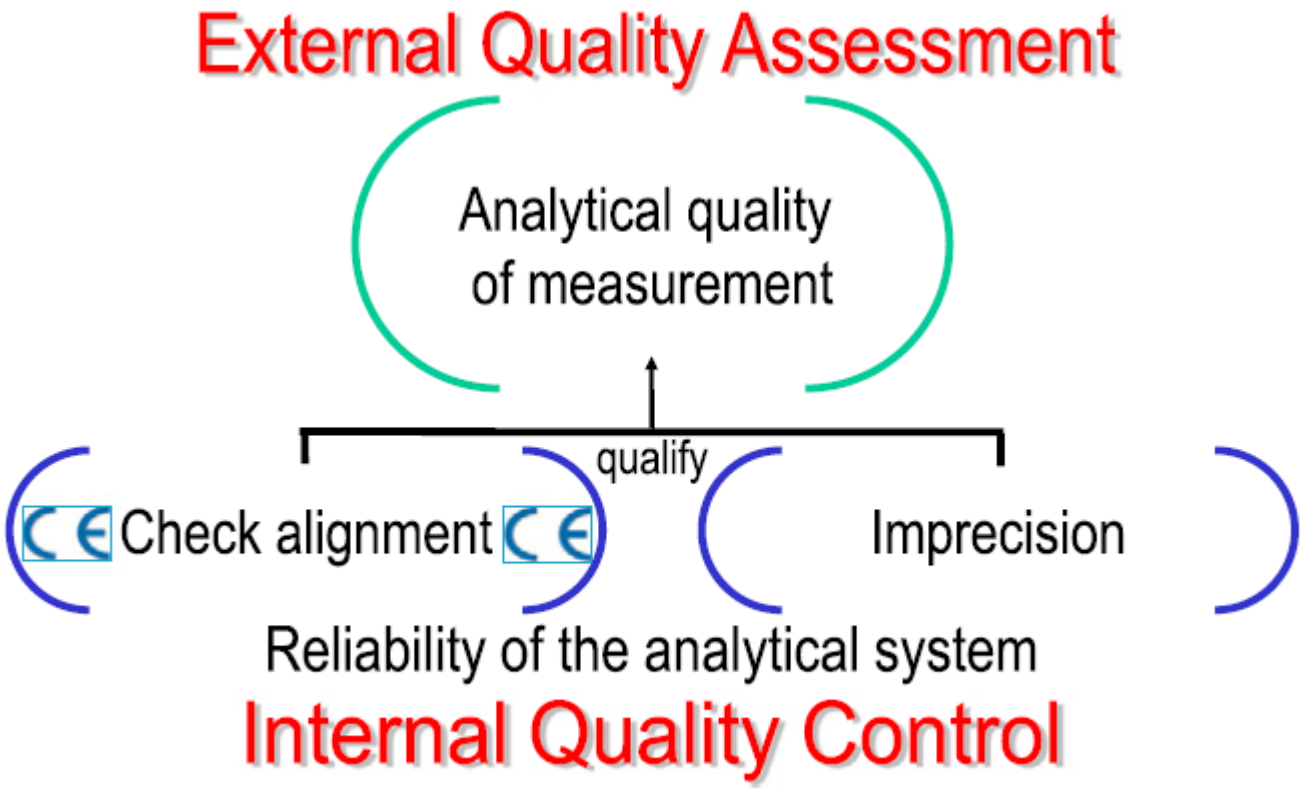



**Fig. 4.** The analytical quality control in the traceability era. Modified from ref. [2].

Braga *et al (2014), CCA; 432: 55 - 61*

The second tool useful to check the alignment of employed commercial systems to available higher-order references is the participation to EQA programs that meet specific metrological criteria. …… Briefly, in addition to the use of commutable control materials, it is necessary to assign values (and uncertainty) to them with reference procedures performed by an accredited laboratory and apply a clinically acceptable TEa limit. …….. Unfortunately there are few EQA programs currently able to fulfill these requirements because of constraints including technical aspects (lack of certified control materials or inability to prepare commutable samples), practical considerations (difficulty of preparing samples covering the full measuring interval and the complicated logistics of preparation and distribution of fresh/frozen samples), psychological limitations (lack of awareness of which quality factors make an EQA important or an unwillingness to adopt them) and economic concerns.

Braga *et al (2014), CCA; 432: 55 - 61*

The main purpose of an optimal EQA program must be to evaluate the analytical quality of laboratory measurements, including the traceability of the calibration and of patient results and the equivalence among laboratories for the obtained results. EQA schemes are therefore in a unique position to add substantial value to the practice of Laboratory Medicine, by identifying analytes that need improved harmonization and by stimulating and sustaining standardization initiatives that are needed to support clinical practice guidelines.

Cited ref.

Miller WG, Jones GR, Horowitz GL,Weykamp C. Proficiency testing/external quality assessment: current challenges and future directions. Clin Chem 2011;57:1670–80.

| **Adam Uldall Lecture** | **Moderator: Anne Stavelin** | *16.30 – 17.30* |
|---|---|---|
| *16.30 – 17.30* | The role of EQA in the verification of in-vitro medical diagnostics | Mauro Panteghini |

Braga *et al (2014), CCA; 432: 55 - 61*

**Table 3. Evaluation capabilities of PT/EQA related to scheme design.**

| | Sample characteristics | | | Evaluation capability | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Accuracy | | | | | | |
| | | | | Individual laboratory | | | | | Standardization or harmonization[b] | |
| | | | | | Relative to participant results | | Reproducibility | | Measurement procedure calibration traceability | |
| Category | Commutable | Value assigned with RMP[a] or CRM | Replicate samples in survey | Absolute vs RMP or CRM | Overall | Peer group | Individual laboratory intralab CV | Measurement procedure interlab CV | Absolute vs RMP or CRM | Relative to participant results |
| 1 | Yes | Yes | Yes | X | X | X | X | X | X | X |
| 2 | Yes | Yes | No | X | X | X | | X | X | X |
| 3 | Yes | No | Yes | | X | X | X | X | | X |
| 4 | Yes | No | No | | X | X | | X | | X |
| 5 | No | No | Yes | | | X | X | X | | |
| 6 | No | No | No | | | X | | X | | |

[a] RMP, reference measurement procedure; CRM, certified reference material.

[b] Standardization when patient results are equivalent between measurement procedures and calibration is traceable to SI by use of a reference measurement procedure; harmonization when patient results are equivalent between measurement procedures and calibration is not traceable to a reference measurement procedure.

Miller *et al* (2011) Clin Chem; 57:1670–80.

# Traceability in EQA

## Added Value !

## BUT

**Maybe for only 20% of the measurands traceability will be feasible.**