



Lessons from External Quality Assessment

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Outline

Reference: ISO 15189:2012

Medical laboratories -Requirements for quality and competence

- Interlaboratory comparison
- Function of EQA
- Evaluation of EQA

Interlaboratory comparisons

ISO 15189:2012; 5.6.3.1 Participation

1. The laboratory shall establish a documented procedure for interlaboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the interlaboratory comparison program.
2. Interlaboratory comparison program(s) chosen by the laboratory shall, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process

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ISO 15189:2012; 5.6.3.1 Participation

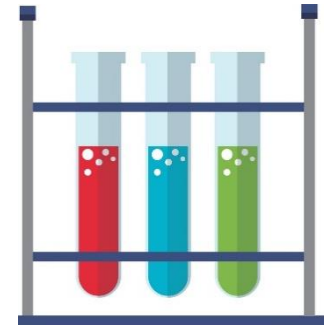
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External Quality Assessment (EQA)

ISO 15189:2012; 5.6.3 Interlaboratory comparisons

The laboratory shall participate in an interlaboratory comparison program (such as an external quality assessment program or proficiency testing program) appropriate to the examination and interpretations of examination results.

Analysis of interlaboratory comparison samples



ISO 15189:2012; 5.6.3.3 Analysis

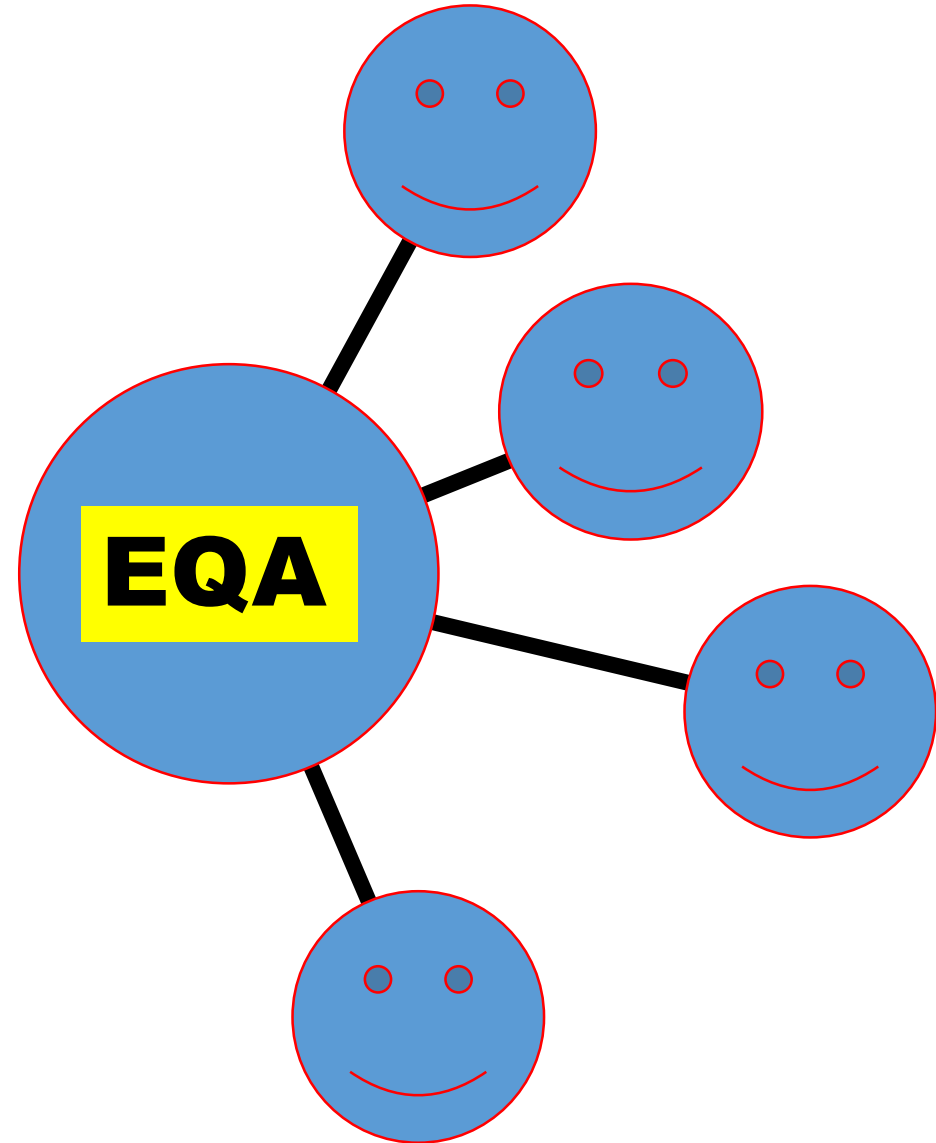
1. EQA sample handling same as patient samples.
2. Performed by personnel using same procedures as those used for patient samples.
3. Shall not communicate with other same EQA participants.
4. Shall not refer to other lab for confirmatory examinations.



What are the features of EQA?

- EQA allows a laboratory's testing to be compared to a source outside the laboratory. Comparison:
 - a) to the performance of a peer group of laboratories or
 - b) to the performance of a reference laboratory or
 - c) interlaboratory comparison with examination of specially provided samples.
- The term EQA ↔ Proficiency Testing

EQA is defined as a system for objectively checking the laboratory's performance using an external agency



Proficiency Testing

- External agency sends unknown samples for testing to laboratories;
- Results of all laboratories are
 - analyzed,
 - compared, and
 - reported to the laboratories.

Proficiency Testing

PTs are organized regularly to assess the performance of analytical laboratories and the competence of the analytical personnel.

Alternative EQA

ISO15189:2012; 5.6.3.2 Alternative approaches

- Rechecking or retesting- slides that have been read are rechecked by a reference laboratory; Samples that have been analyzed are retested, allowing for inter-laboratory comparison
- On-site evaluation -usually done when it is difficult to conduct traditional proficiency testing or to use the rechecking/retesting method.

Morphologic Consistency

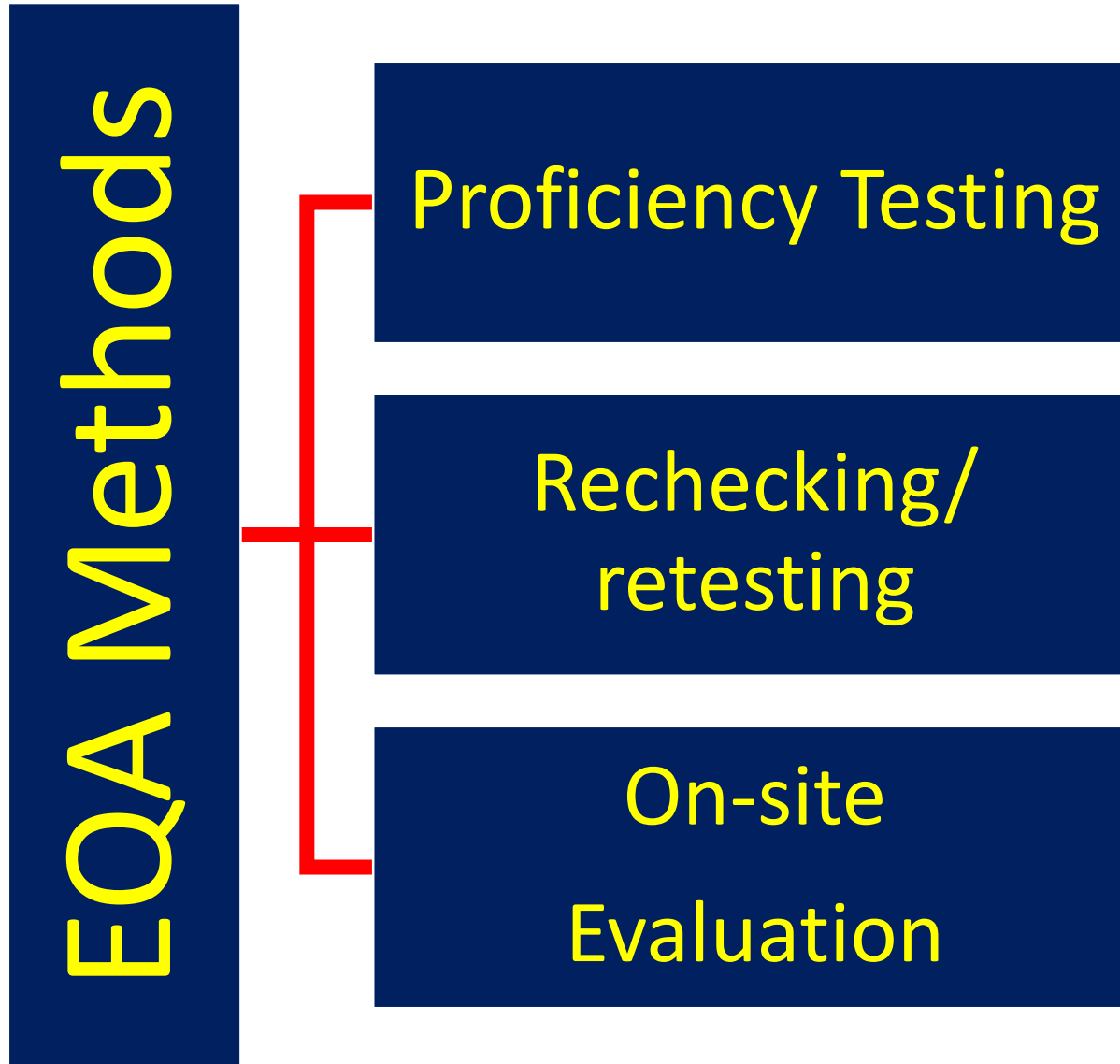
- Multiple lab staff examining slides.
- Need same cellular conclusion.

How to do it:

1. Review unknown slides.
2. Use 35 mm proficiency testing slides.
3. Record answers.
4. Compare to correct PT result.



In summary



Which EQA/PT schemes?

ISO15189:2012; 5.6.3 Interlaboratory comparisons

EQA/PT schemes

- “provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process...”
- Accredited to ISO17043:2010

EQA & ISO17043

ISO17043 standard ensures the EQA scheme is fit for purpose that include:

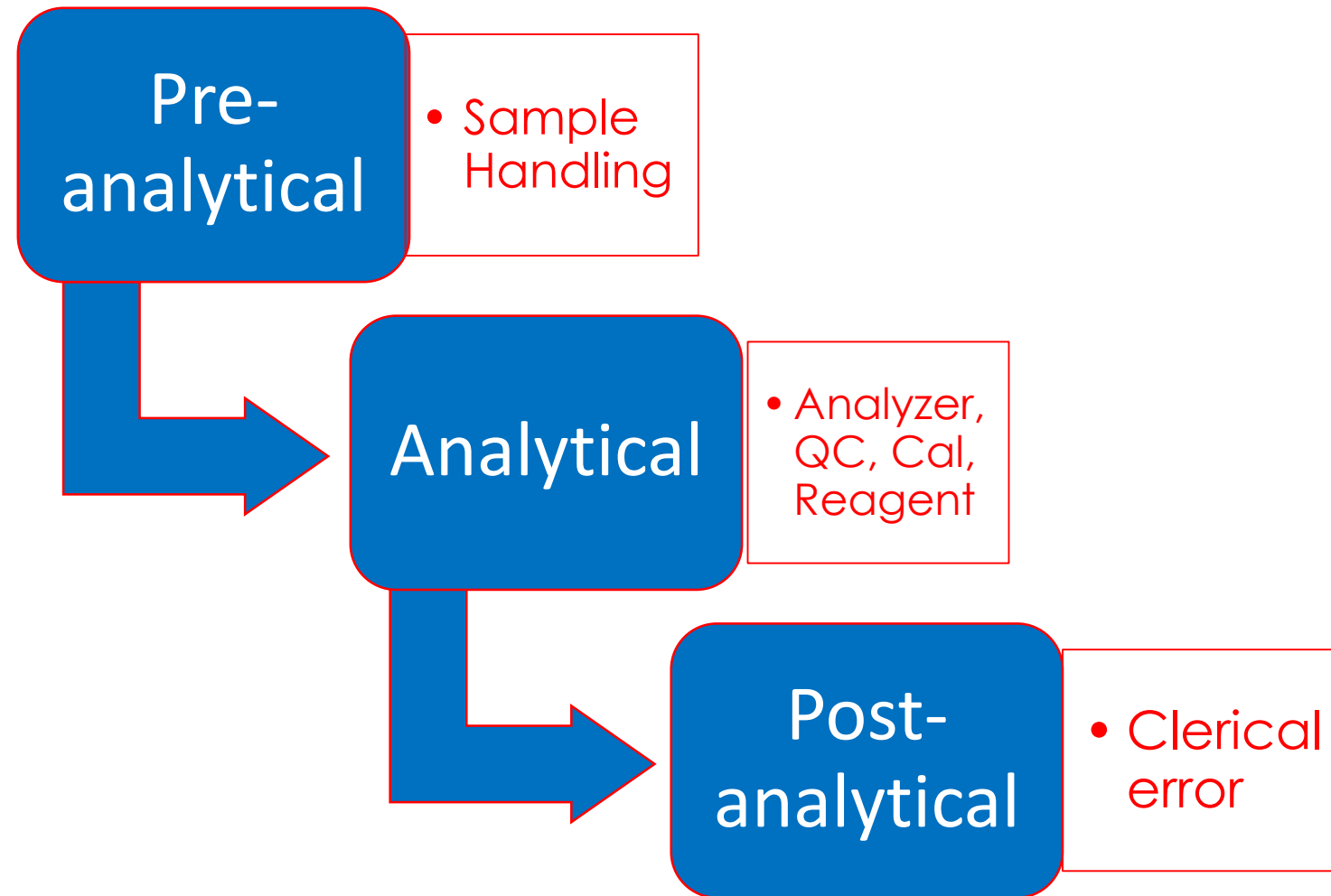
1. design and implementation of the EQA scheme
2. sample quality, manufacture, storage, and transport
3. statistical practices used to determine participant performance
4. participant confidentiality.

EQA: The First Principle



What is entire examination process?

EQA identify pre-analytical, analytical, and post-analytical errors:



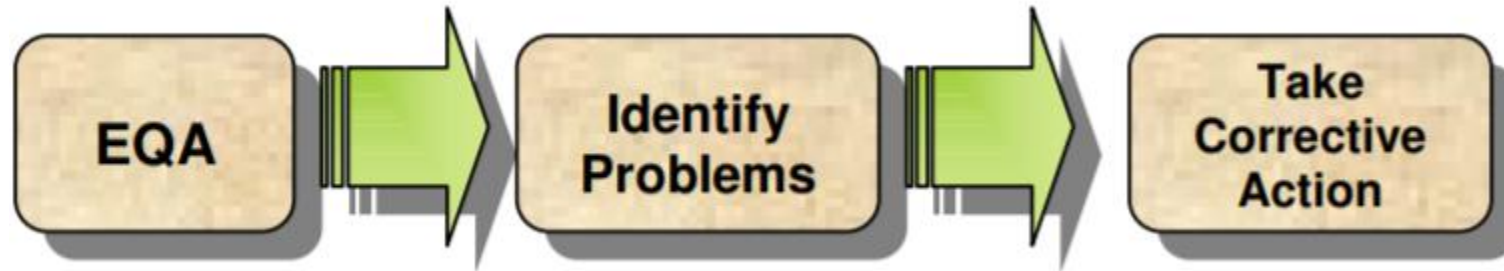
Can EQA detect errors?

- ✓ EQA can also detect deficiencies with IQC.

For example, some IQC providers supply assayed IQC material with wide 2SD often +/- 20 percent from target value.

For this reason, labs may believe their performance is good, but may fail EQA

EQA Corrective Actions



ISO 15189:2012; 5.6.3 Interlaboratory comparisons

The laboratory shall monitor the results of the interlaboratory comparison program and participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled.

EQA performance

ISO 15189;2012; 5.6.3.4 Evaluation of laboratory performance

1. The EQA performance reviewed and discussed with relevant staff.
2. If nonconformities are present, lab to implement and record of corrective action.
3. The effectiveness of corrective action shall be monitored.
4. The returned results shall be evaluated for trends that indicate potential nonconformities and preventive action shall be taken.

EQA has
a number
of functions

It compares
different analytical
methods



Initiates and
evaluates
Corrective Actions



Provides objective
view of test
performance that
IQC alone cannot
provide



It helps laboratories
detect **equipment**
failures, identify
reagent problems
and review staff
competency



It maintains and
improves the
analytical quality
of laboratory



It improves
interlaboratory
agreement and
helps **raise**
standards

Benefits of EQA

External quality assessment program provides information which:

- a. allows comparison of performance and results among different test sites;
- b. provides early warning for systematic problems associated with kits or operations;
- c. provides objective evidence of testing quality;
- d. indicates areas that need improvement;
- e. identifies training needs.

Test EQA sample like a patient

- ✓ Testing personnel
- ✓ Read instructions carefully
- ✓ Check for clerical errors
- ✓ Keep all records and samples

EQA Provider and Participants of National lab, Provincial labs, NGO labs and Private Lab in 2018

Providers	Unit and Participations
PPTC	<ul style="list-style-type: none">• Microbiology 14 labs• Serology 32 labs• Blood Bank 05 labs
1WA	<ul style="list-style-type: none">• Biochemistry 43 labs• Hematology 1 lab
Sysmex	<ul style="list-style-type: none">• Hematology 61 labs

Cost of EQA (2017)

1. NAMRU-2
2. WHO
3. Foundation Merieux
4. Angkor Hospital for Children
5. US CDC
6. MERCY MEDICAL CENTER
7. Center of Hope
8. Biomed Phnom Penh
9. N Health Laboratory
10. Central Hospital Laboratory
11. Royal Angkor International Hospital
12. UHS/JATA Medical Diagnostic Center
13. Professional Medical Laboratory (ProLabo)
14. ANALAB Laboratory
15. Internation Standard Laboratory
16. Sunrise Hospital

Sysmex -2018
= 0\$ FOC

2000 \$USD per lab
Total labs = 61 (?) or \$122,000

EQA summary

