TEHRAN UNIVERSITY OF MEDICAL SCIENCES

External Quality Assurance or Assessment (EQA)

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Quality management system

Quality….

- Quality Control
- Quality Assurance
- Quality System
- TQM science 1990


Quality System
Quality Assurance
Quality Control

Quality Control

- Quantitative and statistical
- Process or system for monitoring the quality of laboratory testing, and the accuracy and precision of results
- Routinely collect and analyze data from every test run or procedure
- Allows for immediate corrective action
- AIM: to reduce both systematic and random error

Quality assurance

- A well defined, organized program design to enhance patient care through the ongoing objective assessment aspects of patient care and the correction of identified problems.

- Planned and systematic activities to provide adequate confidence that requirements for quality will be met.

- Includes IQC, EQA, pre-analytic phase, test standardization, post-analytic phase, management, and organization.

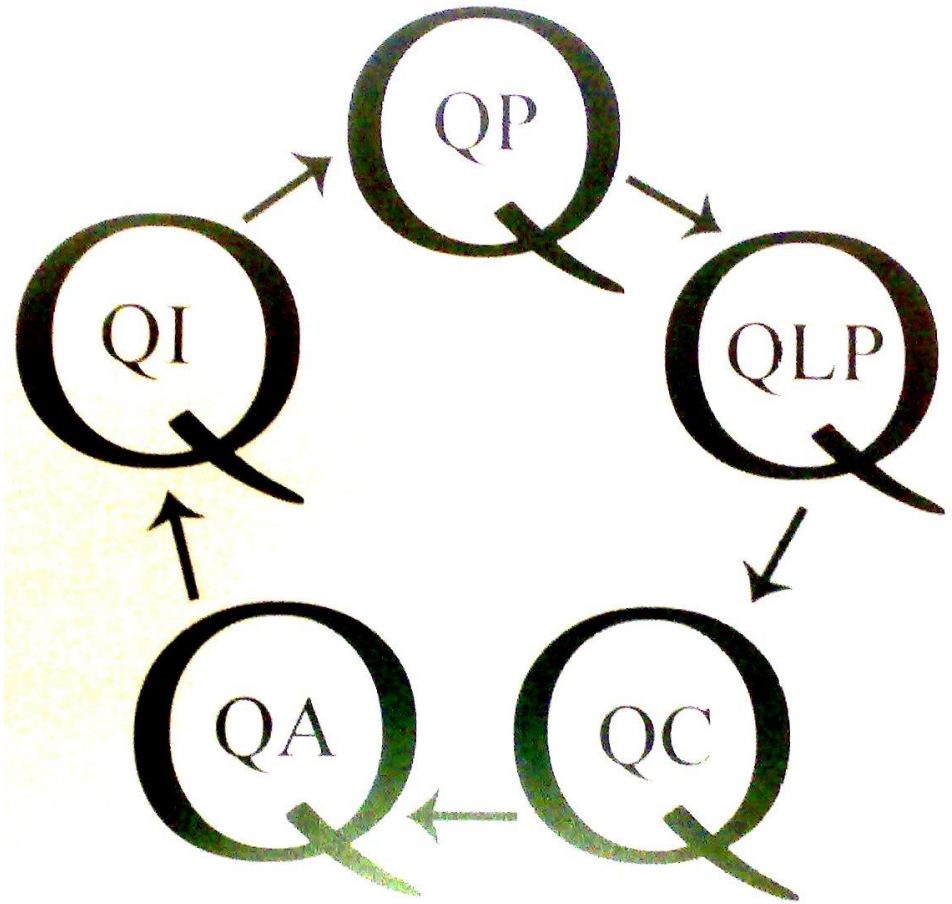
Quality Assurance Program

- Internal Quality Control (IQC) Procedures
- External Quality Assessment (EQA)=PT
- Quality Management

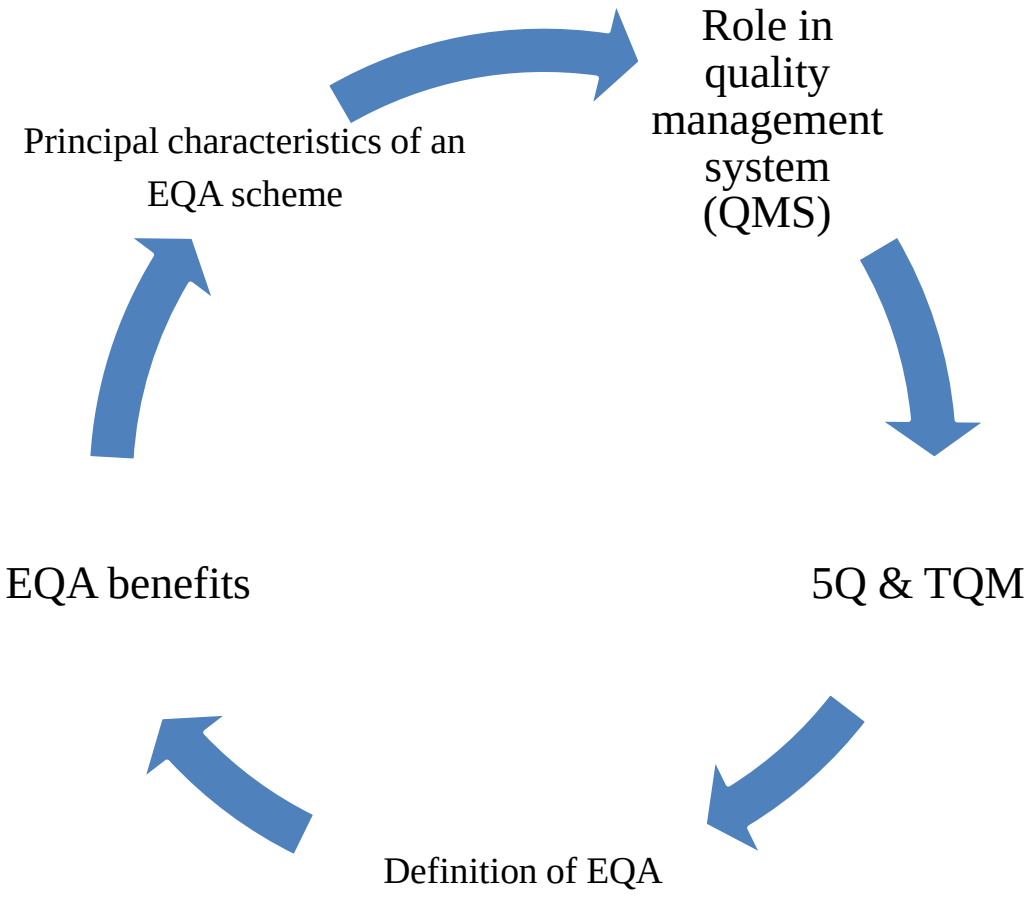
The ultimate goal of quality system is to obtain test results that are Reliable, relevant and reproducible.

TQM new hypothesis: *all persons are manager*

TQM parts= 5Q



Overview of External Quality Assessment (EQA)



Definition of EQA

- EQA defined as a system for objectively checking the laboratory's performance using an external agency
- Evaluation of the analytical performance for every variable involved (staff, equipment, reagents, and method) in comparison with the expected results
- CAP, AAB-MLE, ISO/IEC 17043:2023
- IACLD, Pishgam Iranian

Definitions

ISO/IEC 17043:2023: “Proficiency testing schemes (PTS) are interlaboratory comparisons that are organized regularly to assess the performance of laboratories and the competence of personnel”.

CLSI: “A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory’s results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories”.

Proficiency Testing

- Evaluates past performance
- Covers a range of chemistry, hematology, microbiology, and immunology testing
- Use by laboratories for many years

Principal characteristics of an EQA scheme

EQA is important for improvement of the laboratory quality management system, as it is a measure of laboratory performance.

Proficiency testing process

- Laboratories receive samples from a proficiency testing provider
- This provider may be an organization (non-profit or for-profit)
- challenge samples are provided at regular intervals
- Optimal frequency will be 3–4 times yearly
- Analyze the samples and return their results to the central organization
- Results are evaluated and analyzed
- Compared with other participants
- To make appropriate changes and improvements

Roles of laboratory

- PT instructions must be followed carefully
- Results submission deadlines met
- All PT results, as well as corrective actions, should be recorded and the records maintained for an appropriate period of time
- Must be no difference in the treatment of PT samples and the patient's sample
- PT samples must be processed by normal testing method(s) and involve personnel who routinely perform the testing
- Provider or central organization generally prohibits the discussion of results with other laboratories
- Some PT organizers send different samples to different groups of laboratories to avoid inter-laboratory discussion

Nothing is gained from PT participation unless the information received is directed to improvement in the laboratory

EQA benefits

Allows comparison of performance and results among different test sites

Provides early warning for systematic problems associated with kits

Provides objective evidence of testing quality

Indicates areas that need improvement

Identifies training needs

Limitations

- Not appropriate to use PT as the only means for evaluating the quality of a laboratory.
- PT results are affected by variables not related to patient samples, including preparation of the sample, matrix effects, clerical functions, selection of statistical methods of evaluation, and peer group definition
- PT will not detect all problems in the laboratory, particularly those that address the pre- and post-examination procedures

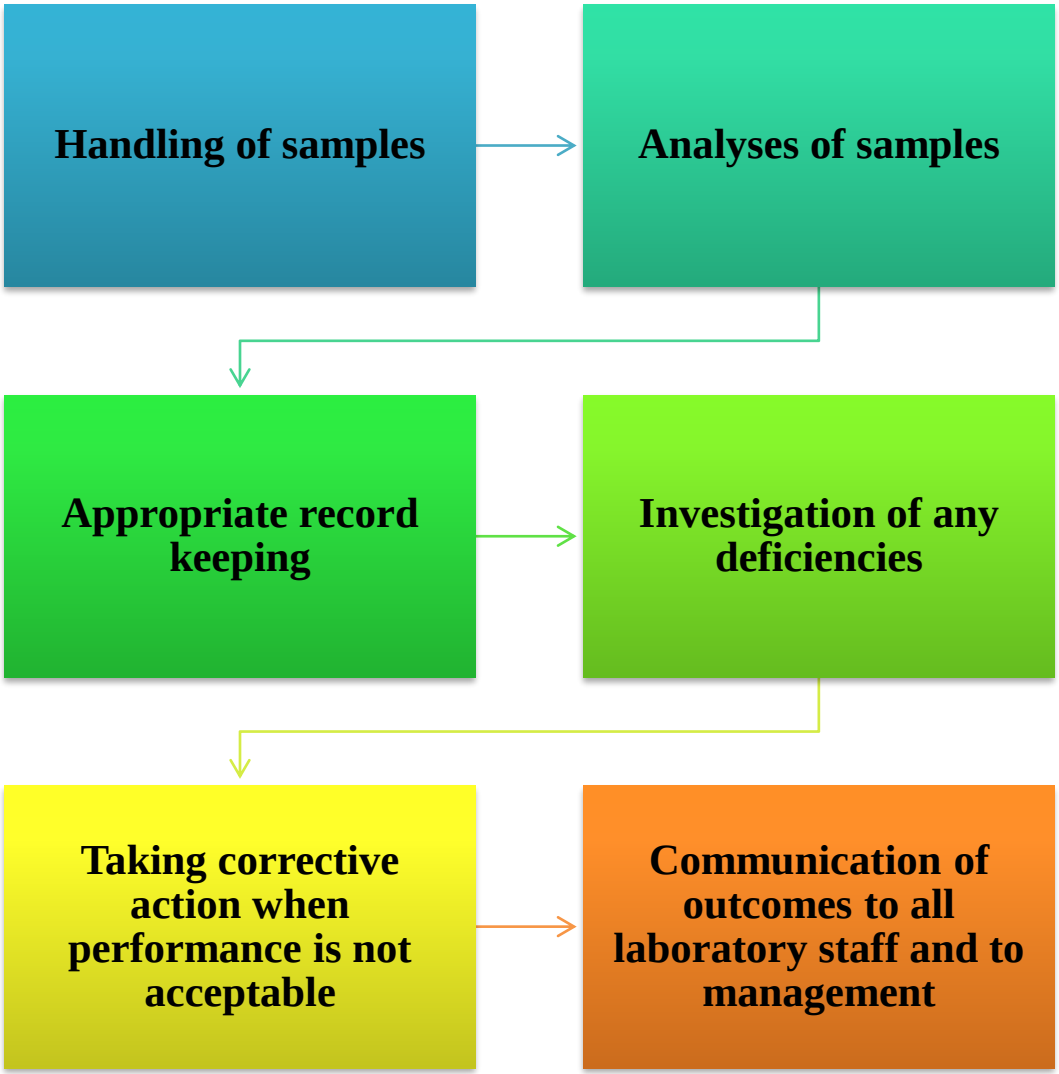
Managing EQA in the Laboratory

Participation in EQA

Management process

EQA performance problems

Management process



EQA performance problems

Pre-examination	• Sample compromised during preparation, shipping, or improper storage/handling in the laboratory • Improper processing or labeling of the sample
Examination	• Matrix effect in EQA challenge materials • Analytical issues: reagents, instruments, test methods, calibrations, calculations • Errors may be random or systemic (require investigation) • Staff competency needs evaluation
Post-examination	• Confusing report format • Incorrect interpretation of results • Clerical or transcription errors

deviation index (DI) or z-score

$$\text{DI (deviation index)} = \frac{actual\ result - weighted\ mean}{adjusted\ sd}$$

- **<0.5 excellent**
- **<1 satisfactory**
- **1-2 satisfactory but borderline careful watch)**
- **2-3 requires review of techniques check on calibration**
- **>3 require urgent investigation**

Feature	Internal Quality Control (IQC)	External Quality Assessment (EQA / Proficiency Testing)
Purpose	Monitors day-to-day precision and stability within the laboratory	Evaluates laboratory accuracy compared to peer laboratories and reference standards
Scope	Detects random errors and short-term performance issues	Detects systematic errors, biases, and long-term performance problems
Comparison Basis	Uses only the laboratory's own control materials and historical data	Compares results with a peer group of laboratories and reference values
Frequency	Performed daily or with every analytical run	Conducted periodically
Responsibility	Managed internally by laboratory staff	Organized by external
Outcome	Ensures consistency and stability of results within the lab	Demonstrates accuracy, reliability, and comparability of results across laboratories
Limitations	Cannot detect consistent bias or systematic errors	Does not monitor daily routine errors inside the lab
Regulatory Role	Supports internal monitoring but not sufficient alone for accreditation	Often required for accreditation (e.g., ISO 15189, CAP)