



Quality System in Health Laboratories

Quality and Quality Assurance

QUALITY of products and services has assumed considerable importance in modern era where everyone expects best products or services. Quality is considered as *the degree of congruence between expectation and realization*. In simpler words, it is the matching of what you want with what you get i.e. *expectations versus fulfillment*. The concept of quality has been elaborated further and an international consensus has been obtained through the efforts of International Organization for Standards (ISO). According to ISO, quality is defined as *totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs*. Quality has also been appropriately referred to as the characteristics of a product or service that make it suitable for the purpose for which it is intended (*fitness for purpose*). Quality has been shown to be synonymous with *consistency* which denotes providing the same product or service time after time, thus making the outcome more predictable. All those activities that are undertaken to assure the quality of a product fall under the broad umbrella of quality assurance.

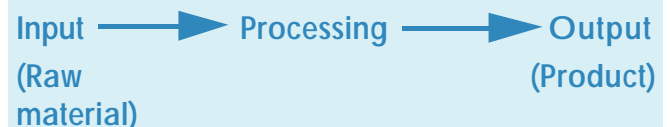
In health laboratory services, the product is the report of the analysis of the material received by the laboratory for processing. The physician or the public health professional utilizes this report for the benefit of the patient or the community. A quality laboratory report thus helps the physician in establishing proper diagnosis rapidly and supports better health care for the patient.

Initially, the quality of the final product was all that was looked at. This soon changed to include the processes that gave the product. From that, a broader view of quality evolved and concepts such as good laboratory practices (GLP) arose followed by customer satisfaction. This has been taken further to the approach of total quality management in which the

focus is on the satisfaction of customers, suppliers, staff and society, and even consideration of environmental issues. To ensure quality, a systematic approach for implementation of mechanism to assure quality and use of tools to assess the quality is adopted. This is the essence of a quality system which utilizes man, management, material, machine, methodology, monitoring and motivation to produce a quality product or service.

Quality System

In any organization, quality is ensured through a well defined quality system. In an industrial unit, the raw materials (input) are processed and transformed into a product (output). A process is defined as the sum total of activities which use resources to transform inputs into outputs. The process may comprise a number of procedures, which is a specified way of carrying out an activity. Each procedure is undertaken in such a way that it delivers the desired result through a quality system approach.



Health laboratories also work on similar principles. The clinical (or environmental) material constitutes the raw material (inputs) which is processed in the laboratory to generate an output in the form of a report. Health laboratories also strive to assure quality of their product (report). However, systematic efforts through the organizational structure and efficient utilization of resources through all the steps to generate quality reports is required. A quality system is part of an overall quality management that aims at ensuring consistency, reproducibility, traceability and efficacy of the products or services.

The ISO defines a quality system as the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Key elements of a quality system

A quality system has the following key elements:

- Organizational management and structure
- Referential (quality) standards
- Documentation
- Monitoring and evaluation
- Training

Organizational management and structure

The overall responsibility for the design, implementation, maintenance and improvements in a quality system rests with the laboratory management. Quality assurance is the responsibility of all the staff members of the organization. However, the top management needs to make a firm commitment to ensure quality and allocate adequate resources. A quality policy reflects the intention and commitment of the organization to attain quality. The policy can be translated into implementation through a quality plan which, along with the policy, needs to be documented in the form of a quality manual.

Laboratory management delegates responsibility and authority to appropriate individuals who are directly responsible for implementing the quality policy and quality system. It makes available to them adequate resources to efficiently discharge their duties. The inter-relationship between various staff members and their job descriptions are decided by the management.

The management also makes all decisions and strategies related to quality. If the size of the organization requires, and resources permit, a Quality Manager may be appointed to supervise and guide all activities related to implementation of quality. In smaller laboratories, one of the staff members can be given the additional responsibilities of a "quality manager".

Referential (quality) standards

The referential standards are an integral part of the quality system. These aim at ensuring safety and consistency. These need to be followed to meet the regulatory requirements as well as to monitor the functioning of the laboratory.

Both management and technical standards need to be followed to ensure quality. These must also conform to the local laws.

Documentation

Documentation is a record of any information or instructions including policy statements, quality manuals, procedures, specifications, calibration tables, reports, job descriptions, documents of external origin such as regulations, standards and examination procedures etc. These would include information on various media, including the electronic media.

The quality system of a laboratory shall define, document and maintain procedures to control all documents and information (from internal and external resources). The current version of relevant documents shall be available at all locations where operations needed for effective functioning of the quality system are performed.

Monitoring and evaluation

The laboratory management must develop and implement quality indicators to systematically monitor and evaluate the laboratory's contribution to patient care. When the programme identifies opportunities for improvement within the system, the laboratory management needs to take appropriate steps to address them. Error management must be vigorously implemented.

Besides, quality assessment through internal and external audits and participation in external quality assessment schemes should also serve to improve the quality.

Training

The quality system is only as good as the staff who actually work with it. No matter how good the quality system is on paper, if the theory cannot be translated into practice, quality cannot be achieved. Staff may need to be trained and this training must also include an understanding of why quality is important. Training should be competency-based and must be followed by post-training support to enable staff to maintain high standards.

Existence of a quality system demonstrates that the laboratory has:

- Commitment to quality;
- A definite programme for quality and its continuous improvement;
- Methods for processing laboratory specimens in the form of approved written Standard Operating Procedures (SOP);

- Evidence-based control systems;
- Appropriate documentation;
- Trained human resource, and
- A mechanism for error management under which it can detect when and where things have gone wrong and take necessary actions to prevent their recurrence.

Assessment of quality system

A quality system can be assessed either through an on-site inspection (audit) or by sending known but undisclosed material to the laboratories for testing (quality assessment scheme). The latter can be done within an institute by internal staff (internal quality assessment scheme-IQAS) or through an external agency (external quality assessment scheme-EQAS).

Principles of External Quality Assessment Scheme

The assessment of quality in a schematic way through an external agency using material of known but undisclosed results is called external quality assessment scheme (EQAS). This is considered a powerful tool that challenges the internal quality control measures that are being adopted by the laboratory. EQAS is a tool by which the entire testing process, including the quality of results generated by a particular laboratory is assessed. The main objective of external quality assessment (EQA) is to establish inter-laboratory comparability, which would influence the reliability of future testing. In contrast, the main objective of internal quality control is to ensure day-to-day consistency. Hence, both internal quality control (IQC) and quality assessment are complementary in ensuring the reliability of procedures, their results and finally, the quality of the product.

The external quality assessment scheme compares the performance of different testing sites and is the challenge to other components of the quality assurance system (internal quality control). This assessment is achieved through processing of specimens of undisclosed but known contents, and it measures the accuracy of the results.

EQAS was earlier known as proficiency testing. It is not correct to consider EQAS and proficiency testing as synonymous, since in current terminology, proficiency and testing denotes competence assessment of individuals and not material-driven external assessment.

Objectives

EQAS are organized to achieve the following objectives:

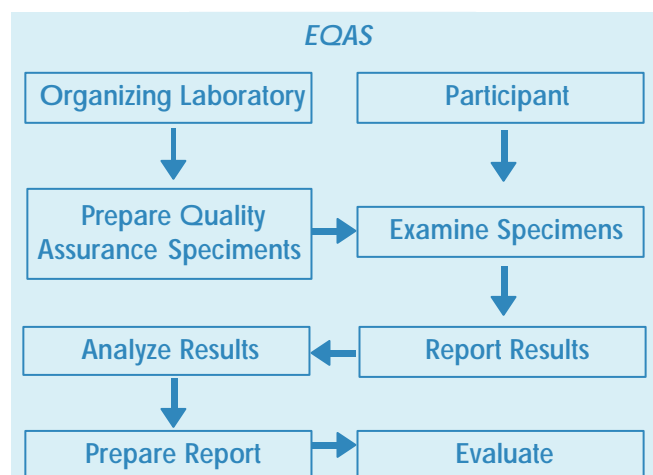
- Monitoring laboratory performance and evaluate quality control measures;
- Establishing inter-laboratory comparability;
- Influencing reliability of future testing;
- Ensuring credibility of laboratory;
- Stimulating performance improvements;
- Promoting high standards of good laboratory practices;
- Encouraging the use of standard reagents/ methodology and trained personnel;
- Identifying common errors;
- Providing mechanisms to remedy deficiencies;
- Facilitating information exchange;
- Supporting accreditation, and
- Educating through exercises, reports and meetings.

Benefits

- Helps laboratories in comparing their results with other laboratories.
- Acts as an educational stimulus to laboratory staff.
- Participation provides credibility to the laboratory.
- Helps the health administrators and regulatory agencies to have an insight into the status of quality of laboratories across the country, identify their problems and devise a methodology to overcome them.

Process

EQAS requires a well equipped, experienced laboratory at the intermediate or central level to act as the organizing laboratory and a fairly reasonable number of laboratories as the participating laboratories. The process of EQAS with important functions of organizer and the participating laboratories has been shown in the figure below.



Basis of success

Various factors that may influence the success of any EQAS are:

- Voluntary participation;
- Confidentiality of individual reports;
- Avoiding provocative statements about the performance;
- Identifying unsatisfactory performers in groups or individuals;
- Providing educational opportunities, and
- Organizer acting as adviser rather than enforcer.

The EQAS are targeted for participating laboratories who are its customers. Their needs have to be met. By participating in the EQAS, the participating units will gain on the following accounts:

- Comparison of performance and results;
- Minimization of errors;
- Self-appraisal;
- Objective evidence of quality/accreditation, and
- Identification of training needs.

Desirable features

The organization of EQAS is a complex task that requires considerable resources and expertise. One must aim to integrate the following features into such schemes:

- Clinical relevance and match with the mandate of laboratories;

- Comprehensiveness: should cover a large number of tests to satisfy the needs of diverse laboratories;
- Versatility: may provide a combination of tests that laboratories can pick up;
- Frequency of distribution should be adequate to allow participants to regularly assess their functioning;
- Material distributed should be derived from clinical source to provide realistic and relevant challenge and must be of required quality;
- Availability of repeat specimens;
- Timeliness of feedback;
- Availability of individual performance data;
- Number of participants should be large enough to ensure reliability of consensus results, and
- Independence of the scheme: should not be influenced by any commercial or industry interest.

Regional EQAS in Blood Safety

The Regional Office, in collaboration with national external quality organizers of Thailand, commenced EQAS in blood group serology and screening for transfusion transmissible infections in 2002. Representative blood banks from various countries of the SEA Region are participating in these schemes which they have been found to be very useful.

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