

## Quality Management

### **What is quality management and what is a quality management system?** <sup>[1]</sup>

A laboratory, just like any other organization, consists of numerous processes in which inputs are turned into outputs through one or more process steps. The core process of the laboratory is the primary process consisting of three stages: the *pre-analytical stage* (the sample is collected, received at the laboratory, registered and processed), the *analytical stage* (the actual laboratory test is performed and the result is recorded), and the *post-analytical stage* (the result is authorized, reported and archived and the sample is discarded/archived).

A *Quality Management System* affects each single process of the laboratory and consists of several layers. You can see this as a pyramid:



The basis of the pyramid consist of *Inspection*. This is nothing more than arbitrary (-partly subconscious-) inspection of work by the laboratory technologist him/herself. Detection of errors depend on alertness of the technologist.

Active, more structured, concious and rational inspection of process performance is called *quality control*. This is the implementation of control steps at strategic logical points in each process of the laboratory to monitor correct performance and quality output. This enables the laboratory to be certain that its final output, i.e. the test result, is of good quality. With quality control errors can only be detected after they have already happened.

*"Quality control is the implementation of control steps to monitor the quality of each process step in each process in the laboratory."*

### **Quality Management System**

A quality management system can be described as a set of building blocks needed to control, assure and manage the quality of the laboratory's processes. A system used in this tool is the framework of 12 building blocks, called quality system essentials (QSEs).



By ensuring that all the processes related to the QSEs perform correctly, quality can be assured. For example: to control and assure quality, good personnel is necessary. The personnel members need to be adequately trained. There should be records of their training in order to be able to prove that personnel members have been trained. Each personnel member also needs to know exactly what he/she needs to do, which is achieved through job descriptions. The performance of personnel members needs to be checked through performance appraisals. Only by doing this, the laboratory can ensure that its personnel members are competent to work in a quality controlled and assured way.

Good quality equipment is also indispensable for good performance of the laboratory. For this an equipment maintenance schedule should be present. Equipment should be calibrated correctly at all times. There should also be procedures in place for when a piece of equipment is functioning incorrectly. Similarly to equipment and personnel a lot of procedures should be in place regarding all the other QSEs. Only by having that, the laboratory can manage the quality of its most important end product: the result to an examination.

The LQSI tool ensures correct implementation of all the procedures of all the QSEs, i.e. the quality management system. In this tool a lot of background information on quality management is included from the Laboratory Quality Management System training toolkit that was developed by the World Health Organization (WHO), Centers for Disease Control and Prevention (CDC) and the Clinical and Laboratory Standards Institute (CLSI). The WHO LQMS follows the QSE structure. The complete WHO LQMS toolkit can be downloaded [here](#). <sup>[2]</sup>

### **What are quality standards and guidelines?** <sup>[3]</sup>

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### **What are quality standards and guidelines?** <sup>[2]</sup>

A technical committee that consists of an international group of experts of the [International Organization for Standardization \(ISO\)](#) <sup>[3]</sup> has formulated requirements for quality and competence in medical laboratories. These requirements were recorded in a document and published as the ISO 15189 quality standard. This standard is internationally recognized and used as the standard for accreditation of medical laboratories: if laboratories have implemented a quality management system that complies with all the requirements formulated in the ISO 15189 standard it can be accredited. The accreditation bodies that assess the compliance of laboratories with ISO 15189 are united in the [International Laboratory Accreditation Cooperation \(ILAC\)](#). <sup>[4]</sup>

As ISO 15189 is an international quality standard, countries can also choose to formulate national quality standards based, or not based on ISO 15189, which can either be stricter or less strict compared to ISO 15189.

Besides quality standards, that merely sum up the requirements to a quality management system, there are also guidelines. These documents are more descriptive, providing more information on the systems approach and philosophy behind the requirements of standards. A good example of a quality guideline is the Clinical and Laboratory Standard Institute's (CLSI) GP26 guideline for implementation of quality management in medical laboratories. The LQSI tool could also be regarded as a guideline.

For more information refer to the WHO Laboratory Quality Management System training handbook by clicking [here](#). <sup>[5]</sup>

### **What is accreditation?** <sup>[6]</sup>

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