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QUALITY MANAGEMENT SYSTEM IN TESTING LABORATORIES

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ABSTRACT

A quality management system (QMS) organizes, regulates, and enhances the factors that affect the laboratory's ability to produce the intended results and the users' level of satisfaction. There are different standards that establish requirements for the implementation of a quality management system for laboratories, and a cross comparison between them is shown. Furthermore, laboratories can benefit from external quality assurance or assessment (EQA) programs in a number of ways, including method validation, results comparison with other laboratories, problem discovery during testing, compliance with accreditation requirements, and credibility. These programs are a tool to maintain strict control over the laboratory operations and all associated variables (people, equipment, and method) in order to control the quality of the procedures. The benefits of external quality assurance programs are examined and various accessible designs are assessed within the framework of a quality management system. However, past benefits won't materialize until each program's reported results are thoroughly examined. A process is proposed because integrating the EQA results into the laboratory's quality management system yields extra benefits. Furthermore, the laboratory's quality management system's internal controls have been proven effective by the outcomes of external quality assurance procedures.

KEYWORDS: External quality management systems, external quality assurance ,quality control , laboratories , harmonization, quality indicators.

INTRODUCTION

A quality management system (QMS) is formed by a series of coordinated activities that are carried out on a set of elements to achieve the quality of the products or services offered to the customer or user. In the case of a laboratory, the accuracy, reliability, and timeliness of the analytical results reported denied its quality, and all aspects of analytical operations should be controlled.[1] The QMS organizes, manages, disseminates, and enhances the components that impact user needs fulfilment and satisfaction as well.[2]

An alternative definition of a QMS is through the meaning of each word separately, according to the ISO 9000:2015 quality management system—fundamentals and vocabulary:

- System: a set of interrelated or interacting elements.
- Management: the planned actions that steer and oversee an organization.
- Quality: degree in which a set of inherent characteristics of an object (product, service, process, person, resource, etc.) meet the requirements (established need or expectation, generally implicit or mandatory).

These three lines lead us to the conclusion that a QMS is made up of the business, planning, and control actions carried out on a set of elements to attain quality. Numerous procedures are carried out in laboratories to ensure the precision, dependability, and traceability of the results, preventing any errors from having an impact on the consumers. A quality management system that monitors, identifies, and controls all those processes is essential.

International Standards for Laboratories

The most generally used international standards in laboratories are those found in ISO 9001, which specifies requirements for the implementation and certification of the quality management system. Documents from the ISO 9000 series offer standards for quality in the manufacturing and service sectors that are applicable to a wide range of businesses. The general requirements for integrating a quality management system [1] in businesses' operations across many productive sectors, including laboratories, regardless of their size, are covered by ISO 9001. the organization characteristics. Because ISO 9001 is a process-based approach, it establishes standard procedures for all activities and organizations, product creation, and service delivery e.g.,

instrument maintenance, documentation control, traceability, etc staff training Specifically, ISO 9001:2015 indicates the issues whose records must be kept:

- 1. The procedures and system of quality management
- 2. Quality goals
- 3. Resource tracking and measurement
- 4. Rivalry
- 5. Observation, appraisal, measurement, and analysis
- 6. Auditing internally
- 7. Management review
- 8. Nonconformity and remedial measures

Furthermore, two ISO standards specifically pertaining to laboratory accreditation will be discussed below:
ISO/IEC 17025:2005. General requirements for the competence of testing and calibration laboratories (Geneva: International Organization for Standardization)

- ISO 15189:2012. Medical laboratories—requirements for quality and competence (Geneva: International Organization for Standardization)

Accreditation is an additional level in quality than certification. In any case, ISO standards were developed as voluntary international rules to standardize various processes for producing high-quality goods and services. Nonetheless, several government organizations currently need accreditation in order to register a laboratory. Thus, in certain nations and in certain industries that generate income, voluntary standards may be become mandatory.

External Quality Assurance Programs

"Programs for "external quality assurance or assessment" (EQA) are a useful tool created by many providers, most commonly scientific or medical societies, with the intention of instructing, assisting, and teaching. They make it possible to compare the actual outcomes with the predicted performance of each variable (workforce, tools, reagents, and technique) in the analysis. In a similar vein, EQA schemes serve as a teaching tool for assessing the laboratory's proficiency in regard to particular factors. EQA is a supplement to internal quality control (IQC) in the quality management system.. Alternatively, proficiency testing (PT) is used as external quality assurance with a regulatory purpose for laboratory licensing and/ or accreditation.[5]

In order to move toward harmonization, EQA programs enable comparing laboratory results and providing information on worldwide variation. Because medical judgments are based on comparing analytical data with time or a reference period, this goal is of utmost importance.[6]

International societies thus acknowledge the significance of EQA provision.[7] A handbook on setting up a national EQA program for medical laboratories and other testing facilities is available from the World Health Organization, and it offers instructions on how to comply with ISO 17043:2010 international standards. Conformity assessment—general requirements for proficiency testing and ISO 13528:2015 Statistical methods for use in proficiency testing by inter laboratory comparison. Contrary to expectations, not enough evidences of quality improvement of the analytical performance as a result of EQA participation have been reported.[8]

Acceptance limits have been classified as[9]:

- Regulatory: for identification of laboratories with a poor performance of the analysis.
- Statistical: an acceptable result is denied by its similarity with others derived from the same method. This type of acceptance limit has the drawback of being method-specific.
- Clinical: based on medical decisions. In case of non regulatory EQA participation, the laboratories should decide the proper limits for the proposed objective. When the acceptance limit is denied as the "fitness for purpose", such purpose must be specified based on external requirements.[11]

Although the ideal frequency of EQA participation has not yet been determined, it is preferable to have a few well-targeted, high-quality schemes with an adequate number of samples than numerous schemes with a high participation rate. Quality of EQA programs depends on the properties of their design.[12] The use of validated commutable samples and the assigned value definition based on a reference measurement procedure or by comparison with a certified reference material makes an EQA program prominent.

Elements of the Quality Management System

A laboratory is a sophisticated system that requires numerous steps and a large number of personnel. The system's complexity necessitates the correct execution of several processes and procedures. Therefore, the QMS model, which looks at the entire system, is very important for achieving good laboratory performance. A "management system to direct and control an organization with regard to quality" is what the QMS is characterized as.[23,24] The QMS covers the laboratory activities, including drug sampling, analysis and reporting. The laboratory philosophy and objectives, system procedures, and guidelines for guaranteeing the quality of the results to satisfy safety and regulatory criteria are all documented in the QMS. To satisfy the needs of the customers. A laboratory requiring ISO compliance must establish, document, implement and maintain a QMS, as well as maintain its effectiveness in accordance with the required compliance standard. The starting point for developing a framework for quality management of Establishing, documenting, implementing, and maintaining a QMS in compliance with the necessary compliance standard is a requirement for laboratories seeking ISO compliance. The introduction to ISO 17025 serves as the foundation for

creating a framework for laboratory quality management. The ISO 17025 addresses every aspect of a quality management system (QMS) in two separate sections: technical requirements and management requirements. Finding the essential components of a quality system is the first step in implementing effective quality management in the laboratory.. These elements need to be integrated with the existing processes and organization, through documentation of standard operating procedures (SOP's) and definition of objectives and policies in a quality manual. A structured approach to the establishment, control, review and improvement of the QMS is presented in Figure 1.

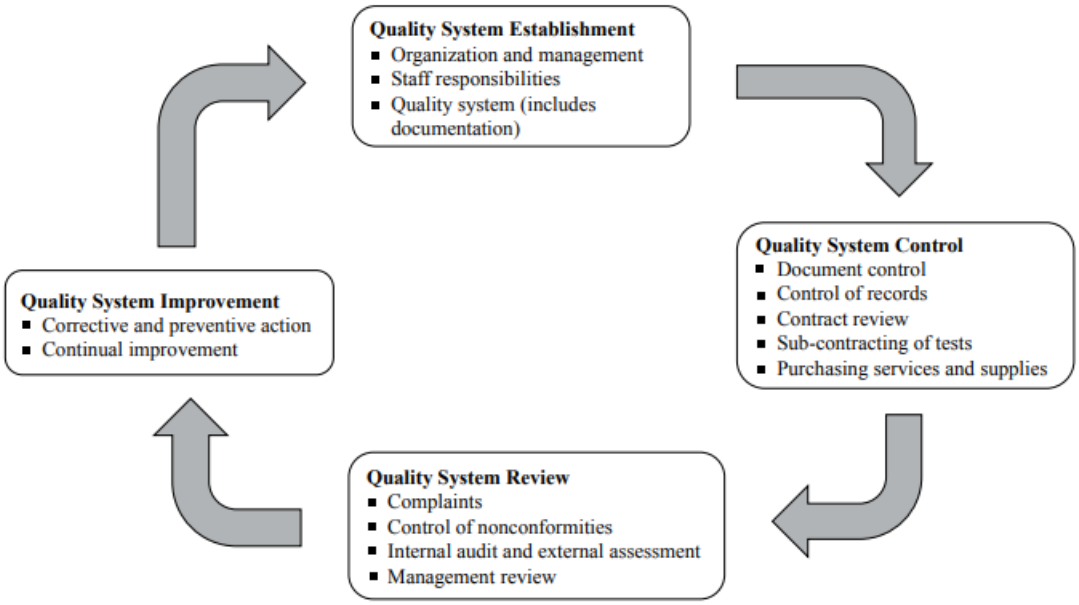

Figure 1. Approach for establishment and improvement of the QMS

Figure 1: Approach for establishment and improvement of the QMS.

Organization and Responsibilities

The laboratory's parent organization needs to be able to be identified legally.. For there to be an effective QMS, organizational structure capable of supporting the elements of the quality policy and quality objectives must be clearly defined.[24] When creating the QMS structure, the company should consider relevant regulatory requirements, the size of the laboratory, the complexity of the materials and products, and other crucial tasks. The robustness of the QMS should be maintained even in the face of modifications. Additionally, it is important to clarify the duties and obligations of the laboratory staff and to identify any conflicts of interest. Effective QMS implementation is the duty of the quality manager. In a similar vein, a technical manager oversees all of the company's technological operations. The right amount of staff is needed to prevent assigning too many tasks to one person, which could lower quality. The company should create job descriptions with precise authority and responsibility definitions that employees can understand.

Documentation

Documenting laboratory policies, methods, and procedures is the main focus of the QMS.. The sequence of documentation required for establishing the QMS is illustrated in a pyramidal form in Figure 2. At the top of the hierarchy of the laboratory documentation is the quality manual which describes the road map to the whole documentation of the laboratory. It describes the technical operations, defined management responsibilities, organization structure of the laboratory, quality policy, QMS requirements, and personnel responsibilities for managing the QMS. procedures for the QMS or reference to them.

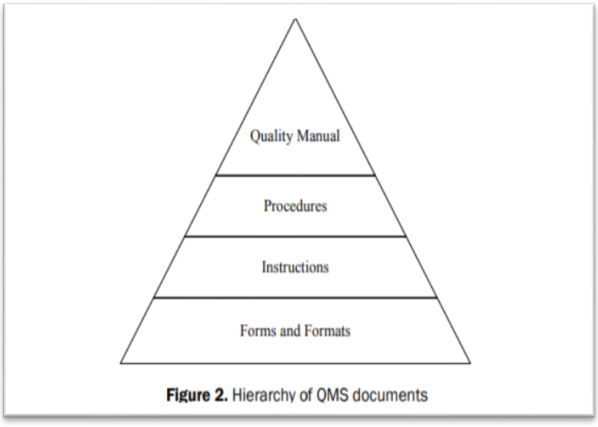

Figure 2. Hierarchy of QMS documents

The laboratory's upper management ought to publicly state that they are dedicated to achieving excellence in every facet of the organization's operations. The laboratory's quality policy is outlined in this declaration. All personnel of the laboratory are responsible for adherence to the quality policy. The policy statement ought to comprise the following: a commitment to

quality and ongoing improvement in laboratory performance; a guarantee that laboratory work will withstand legal and scientific requirements; and a commitment on the part of the laboratory staff to ensure compliance with the relevant standard, such as ISO 17025. The quality policy might be reviewed on a regular basis, but it won't likely change much until the laboratory's main goals shift.

Quality manual also describes the procedures, commonly known as SOP's, for effective implementation of the QMS. SOP's are defined as 'detailed written instructions to achieve uniformity of the performance of a specific function[20] and constitute the second level in the hierarchy of documentation. In simple terms SOP's specify in writing who does the activity and when along with the way to carry out the activity. SOP's establish a systematic way of doing laboratory activities and ensure that activities are performed consistently by all laboratory staff.

The useful daily work instructions are included in this third level of documentation so that they can be easily consulted at the actual work location. Procedures may include instructions that must be followed in order to complete a certain step, or they may refer to instructions that are published independently. The benefit of keeping them apart is that modifications to the instructions don't necessitate alterations to the process.

The final levels in the hierarchy of documentation are the forms. These documents, along with the records generated from them, are an essential component of the QMS since they provide as proof that a process and its associated guidelines have been followed.

Document Control

Document control is a mechanism by which the QMS documents are created, amended, reviewed, approved, and archived to ensure that all laboratory staff uses the latest authorized versions. To be compliant, documents need to have the following essential components: a distinct identity, version control, where every modification to the document needs to cause an increase in the version number, a change history that summarizes the changes made to a document each time it is updated, signatures from the prepare and approval of the document. All controlled document management must be reflected in the procedures that are in place on a daily basis. Only the most recent version of the documents in the QMS should be accessible to staff members while they carry out their responsibilities. To avoid unintentional use, invalid or outdated documents should be swiftly removed from all sites. When documents are stored and shared digitally, they ought to be in read-only forms that can only be modified by authorized personnel.

Control of Records

Records are unique kind of documentation that offer proof of actions taken. They must therefore be observable, distinct, tracable, legible, and established right away following an activity. Records may be categorized as quality and technical records. Quality records include audit reports, customer feedback, corrective and preventive actions, and management reviews. Technical records include the laboratory registers, equipment log books, data recording sheets and reports. The organization ought to have a documented protocol in place for managing its records. These protocols should specify how to locate, store, and safeguard records to prevent degradation and harm. Different record kinds should be given unique identifiers in order to regulate and manage records. This ensures that they are traceable and retrievable. Records should be signed and dated by the person who performed the activity Entries that are corrected should be signed and dated while maintaining the legibility of the original. Automated data capture systems and electronic records must be validated and satisfy the standards for record control.

Internal and External Audits

Systematic, independent, and documented process for gathering evidence and objectively evaluating it to determine the extent to which audit criteria are fulfilled" is how SO defines audit.[23,24] Together with regulatory inspections, audits are an important instrument for assessing the efficacy of QMSs. There are two types of audits: internal and external.. Internal audits are conducted by or on behalf of the organization itself. Independent external organizations conduct external audits, sometimes referred to as external evaluations. It is important to explicitly identify the audit's aim, scope, and criteria. Crucially, auditors should not audit their own work since they could have conflicts of interest that could negatively impact the audit. The company should have a documented SOP outlining the reasons for audits, which should cover the following: duties for the audit program, auditor qualifications, audit frequency, and guidelines for planning an audit, audit reports and follow-up. Audits should be performed at least once a year according to a schedule and discussed during management reviews.

CONCLUSION

A well-organized laboratory with distinct staff roles and an effective communication system is the result of establishing standardized operations for technical support and laboratory administration. Increased internal control, a robust tracking system for all laboratory procedures, an effective and regulated documentation system, and a dependable infrastructure for tracking down errors and complaints are all benefits of implementing the QMS. Adopting important quality indicators facilitates the quick discovery of system flaws and issue solutions. Adoption of standards also contributes to greater time savings and decreased operating costs. The main driver of these cost savings is the higher level of staff competency. Furthermore, we have seen a significant decrease in client complaints and sample rejection, as

well as an improvement in our performance on external quality proficiency testing.

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