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(REVIEW ARTICLE)

A review on quality management system in laboratory testing

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Abstract

A Laboratory Quality Management System (LQMS) refers to a set of policies, procedures, and practices implemented in a laboratory to ensure consistent quality and accuracy in its operations. Continuous improvement of laboratory quality service is vital to ensure accuracy, reliability, and timeliness of laboratory results. Implementation of the quality management system is an effective way of monitoring and assuring laboratory quality service. Various standards and regulations outline specific requirements for implementing a Quality Management System (QMS) in a laboratory environment, such as ISO 15189:2022, ISO 17025:2017, and FDA 42 CFR Part 493. These standards provide guidelines and criteria for laboratory processes, including testing, calibration, documentation, personnel competency, and overall quality control. This article will discuss the applicable standards and legislation, the 12 essential elements of laboratory QMS, and the role of QMS software in a laboratory environment. The objective of this study is to assess the impact of laboratory quality management system implementation on improving quality laboratory service.

Keywords: Quality management system; 12 Essentials of quality management system; Managing laboratory specimens; International standards applicable to laboratory; Implementation of laboratory quality standards; Development of quality system

1. Introduction

1.1. Quality

Laboratory quality can be defined as accuracy, reliability and timeliness of reported test results. The laboratory results must be as accurate as possible, all aspects and requirements of the laboratory operations must be reliable, and reporting must be timely in order to be useful in a clinical or public health setting.

1.2. Quality management system

A quality management system can be defined as “coordinated activities to direct and control organization with regard to quality”. This definition is used by the International Organization for Standardization (ISO) and by the Clinical and Laboratory Standards Institute (CLSI). Both groups are internationally recognized laboratory standards organizations. In a quality management system, all aspects of the laboratory operation, including organizational structure, processes and procedures, need to be addressed to assure quality.

2. Quality system essentials

When all of the above laboratory procedures and processes are organized into an understandable and workable structure, the opportunity to ensure that all are properly managed is increased. The quality model used here organizes all of the laboratory activities into 12 quality system essentials. These quality system essentials are a set of coordinated

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activities that served as a building blocks for quality management. Each must be addressed if overall laboratory quality improvement is to be achieved. This quality management system model was developed by CLSI (Clinical and Laboratory Standards Institute) and is fully compatible with ISO standards.

2.1. Organization

In the quality management model, the term "organization" refers to the management and supporting organizational structure of the laboratory. One of the fundamental components of a quality system, organization is closely tied to each of the other components of the model**.** The following organizational requirements are crucial for developing an effective quality system:

- Leadership - laboratory leaders must be wholly dedicated to putting the system into practice. These leaders also need vision, team-building and motivating skills, effective communication skills, and the capacity to manage resources responsibly.
- Organizational structure - The organizational structure should be clearly defined, and a functional organizational chart should reflect this with roles and responsibilities that are clearly assigned.
- Planning process - Planning skills are required, and planning should consider a time limit, who is responsible for carrying out the tasks, the availability and usage of human resources, workflow management, and financial resources.
- Implementation - Before implementation can begin, the management team must resolve a number of difficulties. These include managing projects and activities, tracking down issues, allocating resources to carry out plans, and making sure that projects / planning should be finished on schedule and meet the organization's aim.
- Monitoring - Processes for monitoring will be required when parts of the quality management system are implemented to make sure that the system is operating efficiently and that benchmarks and standards are being fulfilled in accordance with standards.
- Each laboratory must have an organizational chart (organogram) that describes the management and supervisory arrangements in the laboratory. This chart must be understood by all laboratory staff. Each laboratory must have a head (Laboratory Manager or Director) who is overall responsible for laboratory operations including the following:
- Ensuring that the laboratory complies with all applicable national legal and regulatory criteria;
- Ensuring that there are enough suitably skilled personnel and qualified technical employees;
- Designating a staff member (Quality Manager - QM) in charge of quality management who regularly reports to the laboratory director (at least twice a month, and more frequently if necessary)
- A staff member is appointed to serve as the safety officer
- Supplying a suitable laboratory setting, including facilities and reports;
- Supplying necessary equipment and assuring its operation;
- Ensuring a sufficient supply of reagents, test kits, chemicals, and other supplies for the lab;
- Establishing an efficient system for recordkeeping and documentation, as well as safeguarding the privacy of patient data;
- Establishing an efficient quality management system (QMS) that addresses
- Ensuring effective communication with laboratory users, including clients and patients, in all parts of operations.

2.2. Personnel

The most crucial laboratory resource is personnel. Integrity-driven individuals who value their work and take part in continual improvement are essential to the quality management system's implementation. Laboratories are crucial collaborators in the medical industry. Local resources - When planning internal continuing education programs, local resources offered by the medical industry should be considered.

Some of these resources include:

- quality assurance committee
- clinicians
- nurses
- pathologists
- infection control personnel
- epidemiologists or surveillance officers

- external assessors.

Each of these groups may offer specialized knowledge and experience they can share with laboratory staff. They can be invited to give lectures, lead discussions and exchange information.

2.2.1. External resources

External continuing education programs can also be presented by topic experts, such as those associated with:

- proficiency testing services
- manufacturers
- scientific societies
- World Health Organization
- United States Centers for Disease Control and Prevention
- nongovernmental organizations.

3. Equipment

Equipment management is one of the important elements of a quality management system. Proper management of the equipment in the laboratory is necessary to ensure accurate, reliable and timely testing.

The benefits of a good equipment management program are as below:

- It supports sustaining and enhancing superior laboratory performance;
- It will lessen test result fluctuation and increase the technology person's trust in the correctness of test results;
- It reduces the cost of maintenance because well-maintained instruments require fewer repairs;
- It lengthens instrument life;
- It will reduce interruption of services due to breakdowns and machine failures;
- It will increase safety of employees & workers;
- It will help to increase greater customer satisfaction.
- As the laboratory puts an equipment management program in place, the following elements should be considered.
- Equipment selection and purchase - What standards should be followed when choosing new equipment or instruments? Should equipment be bought or is leasing preferable?
- Installation - Who will install the new instrument and what are the installation criteria for new equipment?
- Calibration and performance assessment - What are the requirements for calibrating the apparatus and determining whether it is running properly or not? What processes will be followed for both new and old instruments?
- Maintenance - What maintenance regimen does the manufacturer suggest? Will the laboratory require any additional preventative maintenance techniques? Are current maintenance practices being carried out correctly? Will labs need to be maintained during a breakdown?
- Troubleshooting - For each instrument, is there a clear process for troubleshooting, or not?
- How much does service and repair cost? Can the lab get the necessary maintenance and repair on site?
- Equipment retirement and disposal - How should outdated equipment be disposed of when it has to be replaced? or was fixed.

4. Inventory and purchasing

Managing inventory and purchasing is a crucial and integral part of the quality management system.

Reagents, supplies, and services must always be available for efficient and economical laboratory operations. Policies and processes must be set up for managing all essential items and services if inventory management and purchasing are to be successful.

Some of the key components to address are:

- vendor/manufacturer qualifications;
- purchase agreements;
- receiving, inspecting, testing, storing, and handling of materials
- tracking materials to individual patients
- assessing and maintaining inventory;
- controlling expiry periods or life cycle
- dispatching supplies to satellite laboratories.

5. Process Control (Sample management, Quality control for quantitative test)

5.1. Process control (sample management)

One of the fundamental components of a quality management system is process control, which includes sample management.

Only the quality of the samples used for testing determines the quality of the work a laboratory produces. The laboratory must take proactive steps to ensure that the samples it collects and receives comply with all standards for obtaining reliable test findings.

The laboratory handbook must have written policies for sample management that have been created.

Components to be addressed include:

- Information needed on requisitions or forms;
- Handling urgent requests;
- Collection, Packaging and labelling, preservation and transport;
- Safety practices (leaking detection)
- Evaluating, processing and tracking of samples;
- Storage, retention and disposal.

5.2. Process control

Process control, a crucial component of the quality management system, refers to the supervision of actions taken during the handling of samples and examination procedures in order to guarantee accurate and trustworthy testing. Process control includes sample management and other quality control (QC) procedures. The examination (analytic) step of testing is being watched over by QC. Before patient results are presented, QC aims to identify, assess, and fix mistakes caused by test system failure, environmental factors, or operator performance.

5.3. Process control (quality control for quantitative tests)

Quantitative tests measure the quantity of a substance in a sample, yielding a numeric result.

5.4. Process control (quality control for qualitative and semi quantitative procedures)

Examinations classified as qualitative include those that gauge a substance's presence or absence or assess cellular characteristics like shape. The outcomes are described rather than quantified, using phrases like "positive," "negative," "reactive," "nonreactive," "normal," or "abnormal."Similar to qualitative evaluations, semi quantitative examinations do not precisely measure the quantity of a chemical. The distinction is that the findings of these tests are presented as a quantification of the amount of a drug that was tested. There are **ti**mes when this estimate is given as a number. Therefore, test results for semi quantitative tests may be shown as “trace amount”, “+1, +2 or +3”.

6. Information management

A system for managing data, including both incoming and outgoing patient information, is known as information management. The information management system could be totally manual, entirely digital, or a hybrid of the two. Information management, another requirement of a quality system regardless of the technology used, is intimately tied to documents, data, and records. Keep in mind that the laboratory's final product is data, reports, and records,

particularly test results. The availability, accuracy, timeliness, security, confidentiality, and privacy of patient information must all be achieved by the laboratory, and this requires that the director of the laboratory make sure that the laboratory has an efficient information management system in place. When planning and developing an information management system, whether it is a manual, paper- based system, or an electronic system, there are some important elements to consider:

- Different identifiers for patients and samples
- Standardized test request forms (requisitions)
- Reports and worksheets
- Checking of process to conform accuracy of data recording and transmission
- Protection against loss of data
- Protection of patient confidentiality and privacy
- Effective reporting systems
- Effective and timely communication.
- Laboratory records include but are not limited to the following:
- Request forms
- Results and copies of reports
- Instrument print-outs
- Laboratory workbooks and worksheets
- Laboratory registers (logbooks)
- Calibration records and calculation factors
- QC records: quality manual, IQC register, results of inter laboratory exchanges of material, EQAS records
- Incident book, corrective action reports
- Stock cards and supply records
- Personnel records: staff training, competency records and health records
- Complaints and their resolution
- Notes and minutes of all formal meetings
- Inventory (or assets)
- Safety manual
- Budgets
- SOPs
- Workload and surveillance reports.

7. Documents and records

Documents provide written information about policies, processes and procedures. Characteristics of documents are that they:

- Information must be given to everyone who requests it, including laboratory employees, patients, and management personnel;
- need to be updated, revised or maintained;
- must be changed when a policy, process or procedure changes;
- provide structures for information reporting and recording through the use of standardized forms; once forms are used to capture data, they become records.

7.1. Quality manuals

The quality manual is a document that describes the quality management system of an organization (ISO 15189). Its purpose is to:

- clearly communicate information
- serve as a framework for meeting quality system requirements
- to give managerial commitment to the quality system.

7.2. Standard operating procedures (SOPs)

SOPs are also documents, and contain written step-by-step instructions that laboratory staff should carefully follow when performing a procedure. A laboratory will have many SOPs, one for each procedure performed in the laboratory.

7.3. Records

Records are laboratory information, either written by hand or printed. They are permanent, and are not revised or modified. They should be complete, legible and carefully maintained, as they are used for many purposes, such as:

- Continuous monitoring – continuous monitoring is impossible to carry out without access to all the data gathered as part of a quality system procedure.
    - Sample tracking: This is essential for troubleshooting, identifying problems, and looking for the sources of testing errors. Well-kept records enable sample tracking throughout the whole testing process.
    - Analyzing issues – Well-kept equipment records will enable a full analysis of any issues that may arise
    - Management – A sound record-keeping system is a crucial management tool.
- Never change a record. If new information needs to be added to a record, it should be noted as an addition, with a date, and signature or initials.
- Different types of records are available in a laboratory. Some examples include:
- sample logbook, registers;
- laboratory workbooks or worksheets;
- instrument printouts—maintenance records;
- quality control data;
- external quality assessment or proficiency testing records;
- patient test reports;
- personnel records;
- results of internal and external audits;
- continuous improvement projects;
- incident reports; or Accident report
- user surveys and customer feedback;
- Critical communications (e.g. letters from regulatory agencies, government or administrative offices within the health care system).

8. Occurrence management

Management of occurrences is essential to ongoing development. It is the method by which errors or nearly errors (also known as near misses) are recognized and dealt with. An occurrence management program aims to improve the process so that errors can be averted by fixing testing or communication issues that arise as a result of an event.

A well-managed laboratory will assess its procedures and identify any process issues that may one day result in a mistake, allowing for the error's prevention.

8.1. Pre-examination errors

Some examples of pre-examination errors that are frequently seen include:

- collecting the faulty sample;
- mislabeling or failing to label the sample;
- storing the sample improperly prior to testing, so that the sample deteriorates;
- transporting the sample under conditions that damage the sample or that endanger staff and public safety;
- Damaging the reagents or test kits by storing them improperly.

8.2. Post-examination errors

Common examples of these kinds of errors include:

- making a transcription error when
- rebuild the report;
- producing a report that is illegible, usually caused by poor handwriting, but sometimes by damage to the report form;
- sending the report to the wrong location, which often results in complete loss of the report;
- failing to send the report.
- Examples of errors that can occur in each phase are given below:

8.2.1. Pre-analytical phase

- Incorrect test request or test selection
- Incomplete laboratory request forms
- Incorrect specimen collection, labelling and transportation

8.2.2. Analytical phase

- Use of faulty equipment, improper use of equipment
- Use of substandard or expired reagents
- Incorrect reagent preparation and storage
- Incorrect technical procedures; non-adherence to standard operating
- procedures (SOPs) or internal quality control (IQC)

8.2.3. Post- analytical phase

- Inaccurate reporting and recording
- Inaccurate calculations, computation or transcription
- Return of results to the clinician too late to influence patient management
- Incorrect interpretation of result

9. Different Assessment

9.1. Assessment (audits)

One of the 12 elements of a quality system, assessment is crucial. It is a way to analyze a laboratory's quality management system's efficacy through internal and external audits, as well as through performance evaluation in an external quality assessment (EQA) program.

External audits are evaluations carried out by teams or organizations outside of the laboratory. Assessments for licensure, certification, or accreditation purposes may be among them.

9.2. Assessment (external quality Assessment):

EQA is here defined as a system for objectively checking the laboratory’s performance using an external agency or facility.

Several EQA methods or processes are commonly used. These include:

- Proficiency testing: An external source delivers unidentified samples to a number of laboratories for testing, and the laboratories are then given the results of all the laboratories' analyses and comparisons.
- Rechecking or retesting: To allow for inter-laboratory comparison, slides that have been read by a reference laboratory are rechecked; samples that have undergone analysis are retested.
- On-site evaluation is typically used when regular proficiency testing or the rechecking/retesting procedures are impractical.

9.3. Assessment (norms and accreditation):

A laboratory's quality management system effectiveness is evaluated through assessment. The foundation for evaluation is standards and other normative materials that offer guidelines. They may be created at the municipal, national, or worldwide levels. The development of norms and standards as well as the accreditation or certification of laboratories are important aspects of the assessment process.

- Certification— The process through which an unbiased organization provides written confirmation that a good, process, or service complies with legal requirements. A certification body officials visit a lab as part of the certification procedure. These representatives are seeking proof or evidence of adherence to the requirements, regulations, requirements, and policies. The primary stage inspection team looks for actual texts, procedures, and documentation.
- Accreditation— the process by which an authoritative body formally acknowledges that a person or body is qualified to do particular activities. Representatives from an accreditation body inspect laboratories to check

for evidence of adherence to standards, policies, procedures, requirements, and regulations. They also watch laboratory staff in action to make sure they are carrying out their tasks efficiently, correctly, and competently.

Because accreditation also includes a capacity review, it gives users of the laboratory a higher level of comfort that its testing is accurate and dependable.

- Licensure— the authorization to practice, typically granted by a local government body. Typically, licensing is based on evidence of knowledge, training, and abilities. In most cases, having a license to operate a laboratory is necessary by law.

10. Process improvement

One of the key components of a quality system is process improvement, which sets a plan for assisting in the long-term development of laboratory quality. A quality management system must constantly strive to enhance the laboratory operations.

Process improvement is a methodical and dynamic technique to raising the quality of the inputs, outputs, and laboratory products that combines these processes. It is a method for resolving issues.

11. Customer service

The International Organization for Standardization (ISO) standards place a lot of emphasis on customer satisfaction, which is a key component of a quality management system. In the end, the lab creates a product for its clients that contains the test results. The laboratory is not fulfilling its principal job if the customer is not well taken care of. Seeking customer satisfaction requires the following: Commitment, planning, Knowledge, Resources

12. Facilities and safety

The laboratory work area and facilities must be such that the workload can be performed without compromising the quality of work and the safety of the laboratory staff, other health care personnel, patients and the community. The workspace and amenities in the laboratory must be designed such that the task may be carried out without endangering the safety of the laboratory workers, other healthcare professionals, patients, and the general public.

The laboratory must be built with an active ventilation system, enough space for personnel, laboratory carts, and trolleys to move around, and proper air circulation throughout.

To promote optimum ventilation, rooms should have high ceilings and be painted with glossy, washable paint or coated with a material that is easy to clean and disinfect. Additionally, there must be no edges (rounded corners) between the floor and the walls, and the floor must be simple to clean and disinfect. It is crucial that the laboratory's various spaces are clean.

Examples of areas that need daily attention are:

- Benchtops- Benchtops should be cleaned and disinfected following examinations as well as any sample or reagent spills. Typically, the technical personnel who conducts the tests is given this duty.
- Floors—Normally, cleaning staff is responsible for disinfecting the floors at the end of the day, unless restricted access permits only technical staff to do so.

Other areas and premises of the laboratory should be scheduled for cleaning on a weekly or monthly basis, depending on laboratory conditions. For example, ceilings and walls may require cleaning Depending on the state of the lab, other spaces and grounds should be scheduled for cleaning on a weekly or monthly basis. In contrast to objects like refrigerators and storage spaces, which may be planned for a monthly cleaning, ceilings and walls may need to be cleaned on a weekly basis.

Laboratory area cleaning and disinfection should be documented, together with the time and identity of the worker. The laboratory SOPs, which must be established, must specify the cleaning reagents used, their amount used, the cleaning method, the frequency of cleaning, etc.

12.1. Storage facilities

The continued integrity of samples, slides, histology blocks, retained microorganisms, documents, files, instructions, equipment, reagents, laboratory supplies, records, and results should be ensured by providing storage space and circumstances that meet these requirements.

To avoid cross contamination, clinical samples should be maintained in the proper conditions, apart from reagents and tools used during examination procedures.

To ensure the secure storage of extremely harmful pathogens, certain biosafety and biosecurity precautions should be performed.

12.2. Staff facilities

Hand-wash basins, including hand sanitization washrooms and toilets a supply of drinking water and facilities for food storage facilities for storage of personal protective equipment and clothing.

12.3. Patient sample collection facilities

Facilities used to collect patient samples must to have distinct waiting and reception rooms. During collection, care should be taken to accommodate the privacy, needs, and comfort of the patient as well as the needs of any suitable accompanying individuals.

In order to meet the needs of both patients and employees, sample collection facilities should include and maintain the necessary first aid supplies.

12.4. Accommodation and environmental conditions

The laboratory needs to have enough room and be well-organized in order to maintain the standard of the job and the safety of the personnel, patients, clients, and visitors. The proper upkeep of all work places and good housekeeping (overall tidiness, cleanliness, hygiene, freedom from rodents and insects) must be ensured. Equipment and workstations should be set up by laboratory section leaders to facilitate a productive and comfortable workflow.

According to the laboratory's mandate, the lab must have the necessary biosafety infrastructure in place so that it can safely handle microorganisms with varying levels of bio risk.

In accordance with environmental requirements, laboratories must be equipped with the necessary utilities, such as clean running water, lighting both natural and artificial, ventilation, electric outlets, backup power (if needed), drainage systems, and sanitary facilities for both patients and personnel.

To avoid cross-contamination and lower potential safety concerns for all employees and visitors, potentially dangerous operations must be carried out in a separate area. Bacteriology of tuberculosis, handling and analyzing high-risk materials, nucleic acid amplifications, and controlled settings for sizable computer systems and some high-capacity analyzers are a few examples

For samples, slides, histology blocks, histology samples, retained microorganisms, documents, manuals, equipment, reagents and other supplies, records, and results to remain intact, sufficient storage space in the right conditions, including refrigerators and freezers, must be available. Protection from light, dampness, dust, insects, and vermin must also be ensured. Storage spaces need to be sufficiently guarded to deter unlawful access.

Waste management standards must be followed for the safe and efficient disposal of all infectious waste, including sharps. For contagious and non-infectious trash, the laboratory must use separate waste disposal systems. Sharps disposal, the storage of solvents, and the disposal of radioactive waste all require special containers.

13. Managing laboratory specimens

13.1. Pre-analytical phase

Both the sample material's quality and the clinical indications have a significant impact on the end product's quality. Even when the analytical techniques are of high quality, the results from the laboratory will be of low quality if quality assurance measures are not taken at this point.

- Appropriate request forms must be utilized, and they must include information that accurately identifies the source of the sample (for example, the patient) and the authorized person making the test request. To enable adequate result interpretation, clinical information, including treatment, is needed.

Patient identification, gender and date of birth;

- Patient location/source of specimens;
- Identity of the requesting person;
- Type of sample;
- Examinations (tests) required;
- Clinical details, e.g. any drugs/antibiotics being given that may have relevance to the interpretation of results;
- Time and date sample taken.

- Proper management of samples during collection, transport and storage must be ensured according to SOPs, which must address:

Instructions to patients including their fasting state and collection of timed samples;

Type of sample container to be used for various laboratory tests; volume of sample required; any special/necessary additives including anticoagulants;

- Primary sample collection technique;
- Correct labelling;
- Special transport arrangements between the site of primary sampling and the laboratory;
- Safe disposal of materials used to collect primary samples;
- Procedures to be followed if the sample quality is suboptimal or unsatisfactory;
- Recording unusual physical characteristics including lipaemia, haemolysis, icterus, etc.

Every primary sample needs to have a special identification (accession) number that is recorded along with the date and time of receipt. Using the proper laboratory safety precautions, aliquoting samples and subsampling should be performed.

In order for the necessary analysis to be completed, the laboratory must give instructions and oversee the transportation of samples to the lab within the appropriate timeframe, at the appropriate temperature, and in the authorized preservatives.

Transport must be safe for the carrier, the general public, and the receiving laboratory, and it must follow any applicable national or international regulations. Bottles and tubes containing liquid samples, such as blood specimens, should be transported upright and secured in a screwcap container or on a rack in a transport box. Containers containing liquid specimens need to be wrapped with absorbent paper to catch any spills and absorb the liquid.

According to current International Air Transport Association (IATA) requirements, triple packing should be utilized when shipping poisonous, infectious, or dangerous commodities (Infectious Substances Shipping Guidelines, 2006). The proper methods for packaging and transportation should be taught to everyone involved in the shipping process

The laboratory must have a written policy in place for handling samples that were improperly identified. For the acceptance or rejection of specimens, criteria must be created and implemented.

Before the specimen is frozen, aliquots or subsampling should be performed because frequent freezing and thawing of specimens can harm the sample (reduce virus concentration or denaturing antibodies). Be aware that some freezers

have the label "frost free"; these shouldn't be utilized to store specimens since the temperature cycling necessary to maintain them free of ice buildup can harm specimens.

13.2. Analytical phase

The amount of samples to be examined, the facilities, equipment, and staff available, and the careful selection of the examination technique are all crucial.

SOPs must be accessible for all types of analysis. The laboratory must assess the methods to make sure they are appropriate for the necessary examinations. SOPs must be accessible in the required tongue. The information included in the SOPs, and permitted work instructions may be made available at workstations.

The laboratory must have an IQC system to ensure that the expected results quality is met for each batch of tests. If there is non-compliance, action must be done. If the QC findings are outside the pre-set tolerance ranges, this could result in the results of a batch of tests being rejected. When the necessary corrective action has been done in these situations, the samples will need to be inspected again.

13.3. Post-analytical phase

- Designated staff must review and authorize release of the test results.
- Laboratory data should ideally be reported in System International (SI) units and be clear and free of transcription errors.

Laboratory reports should include:

- Identification of the laboratory issuing the report;
- Requester’s identification;
- Type of sample;
- Date and time of primary sample collection,
- Date and time of receipt by the laboratory;
- Date and time of reporting;

Comments on the primary sample which might have a bearing on the interpretation of the result, e.g. haemolysis, icterus, lipaemia, etc.;

Comments on the quality of the primary sample which might invalidate the result, e.g. clotted sample for hematology parameters;

- Method of testing used;
- The results and units of measurement where appropriate;
- Where possible, the normal reference interval (normal range);
- Identity and signature of the person releasing the report.

The laboratory must set up protocols for alerting the requester or physician in charge of the patient's care when important analysis findings go outside of predetermined bounds. With physicians and other service users, these boundaries should be established.

There must be a documented procedure for reporting urgent results by telephone.

Procedures must be in place for the post-examination storage of samples for a predetermined amount of time and for their eventual safe disposal, enabling re-examination if necessary. The required storage period must be followed for all original samples and sub-samples, stained microscope slides, histology specimens and blocks, isolates, and other biological material.

13.4. International standards applicable to laboratories

The quality system's foundation is its adherence to quality standards. They are made to ensure that laboratories are compliant with regulatory requirements, such as local health legislation, and to monitor laboratory operations. security and reliability of operation

Table 1 International standards applicable to laboratories

ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
ISO 15189	Medical laboratories – particular requirements for quality and competence
ISO/IEC 17043	Conformity assessment – general requirements for proficiency testing
ISO 13528	Statistical methods for use in proficiency testing by inter laboratory comparison
OECD GLP	OECD principles on good laboratory practice
ISO Guide 34	General requirement for the competence of reference material producers
ISO 8402	Quality management and quality assurance – vocabulary
ISO 19011	Guidelines for quality and/or environmental management system auditing
ISO 9001	Quality management systems – requirements

Quality standards should be developed in consultation with stakeholders, including significant figures in the MOH and other pertinent government departments, the national laboratory focal point, national regulatory authorities, and significant figures from donors and partner organizations like the WHO, clinical and public health doctors, disease program managers, representatives of pertinent professional societies, research and training institutions, legal advisors, and healthcare providers.

14. Implementing laboratory quality standards

14.1. National level

The following steps are a guide to implementing laboratory quality standards:

- Obtain national agreement for established standards through peer review.
- Obtain permission from the appropriate national authorities for the agreed-upon criteria.
- Create a strategy for implementation that includes short-, medium-, and long-term goals, activities, and dates, as well as a rough annual budget.
- Choose the best organizations to carry out the implementation (the government, nongovernmental organizations, and other partners, including the business sector), and make them aware of the plan and their potential contributions.
- Sensitize the institutions and medical facilities that are participating.
- Use or modify already-existing policies, procedures, record forms and recording formats, appraisal forms, audit checklists, etc.; or create documents that are country-specific.
- Create nationwide protocols for sample referral and laboratory networking.
- Create thorough annual operations plans that include budgets

14.2. Stepwise implementation strategy

- Step 1: Set up a national laboratory quality committee

It is the key group for the initial and continuous situational analysis, capacity building, standards elaboration, monitoring, and continual improvement program of the country.

- Step 2: Set up the national laboratory quality policy

The policy should be a public, professional and political agenda for quality. The policy should include a description of the nation's vision and mission, as well as goals and guiding ideals. It must involve a dedication to responsibility and transparency. Incentives for quality and performance enhancement in the health laboratory system should be included.

- Step 3: Develop national quality standards

The national laboratory quality committee should design a cascade approach for stepwise implementation of the national standards, with consideration of the following principles and activities:

- Promotion of a quality culture;
- integration with stakeholders such as medical laboratories, health authorities, professional societies, providers of external quality assessment schemes, and industry;
- communication with other agencies;
- capacity-building;
- pilot testing;
- provision of adequate tools for the assessment of pilot testing; and
- nationwide implementation.
- Step 4: Develop recommendations and guidelines for stepwise implementation of the quality management system
- Step 5: Design an assessment program for evaluating and monitoring the implementation process

The assessment is carried out using a peer evaluation system that is based on management system and technical assessors who have received the appropriate training. These assessors may come from the professional world or from governmental organizations like the Ministry of Health, laboratory units within the ministry, and other laboratories, such as university laboratories.

External, non-governmental audit organizations (such as certification or accrediting bodies) are subcontracted to carry out the assessment.

Assessment is carried out using a combination of the two above mentioned techniques, using mandated and/or voluntary mechanisms.

- Step 6: Advocate for a national regulatory system for quality assurance of in vitro diagnostic medical devices

14.3. Laboratory level

Individual laboratories will have to follow a similar procedure in order to set the recognized standards. The laboratory manager will need to assume a leadership position and involve every member of staff in the procedure. Reorganization is an example of a change that is simple and inexpensive to make. Other adjustments, including those that demand substantial involvement and money, are more expensive or more challenging to carry out.

Start by making simple and easy-to-implement changes, for example:

Introduce SOPs for particular procedures or activities one by one. This could be sample collection, including phlebotomy, or an SOP for the examination of a particular analyze.

Table 2 Development of a quality system

Quality policy	Mission statement
Quality plan	Implementation of policy
Quality manual	Policy, plan and application of standards
Procedures	Development and application of SOPs
Work instructions	Methodology to carry out specific tasks
Training of staff	Implementation of quality system and use of SOPs
Monitoring and evaluation	Assessment of quality and correction process

15. Quality management system (QMS)

A quality monitoring approach that has been designed with the assistance of the appropriate laboratory employees must be applied to every administrative and technical procedure in the lab. Step-by-step instructions must be used to document each process. Head of laboratories are responsible for ensuring that all documents are understood and all procedures are adequately carried out by laboratory employees. Each document must be signed, dated, and reviewed every year or if a change in process is necessary or carried out.

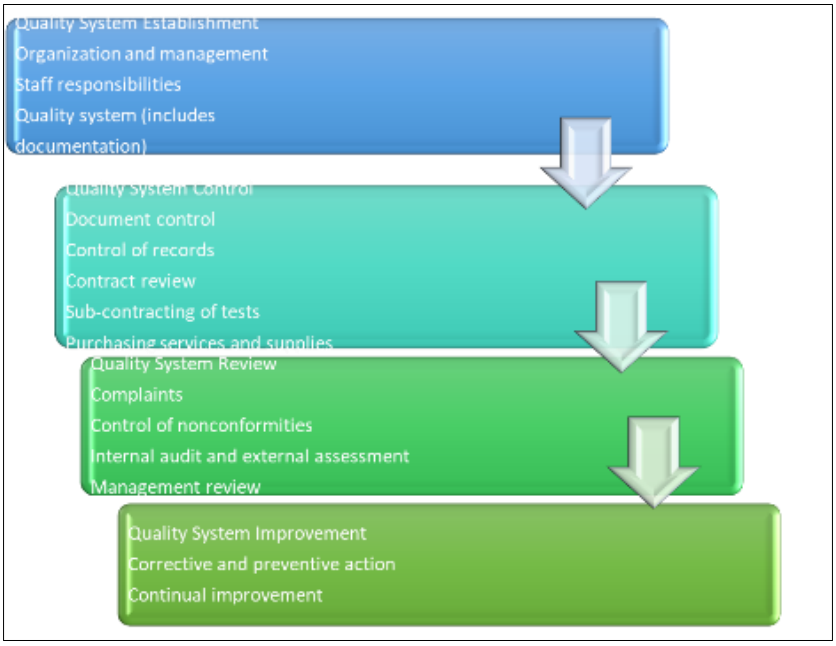

Figure 1 Approach for establishment and improvement of the QMS

15.1. Documentation

All of the policies, protocols, and procedures for the laboratory are documented as part of the QMS. In a pyramidal representation of the paperwork requirements in order to establish the QMS is shown. The quality handbook, which outlines the path to the laboratory's whole documentation, is at the top of the hierarchy of lab documentation. It includes information on the quality policy, the QMS requirements, the lab's organizational structure, the management duties of the laboratory personnel for the QMS and technical operations, and any documented QMS procedures or references to them.

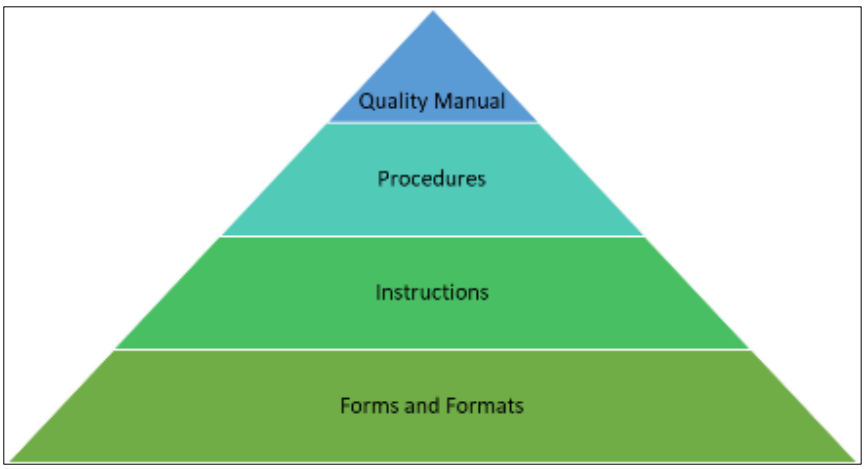

Figure 2 Hierarchy of QMS documents

15.2. Document control

Document control is a process used to generate, modify, evaluate, approve, disseminate, and archive the QMS documents to guarantee that every laboratory staff uses the most recent authorized versions. The following essential components are required for documents to comply: A unique identifier, version control, where any alteration to the document must result in an incremental increase in the version number, a change history that lists the changes made to a document each time it is modified, and signatures from the author and approver of the document are all required. All regulated papers must be managed on a daily basis, and procedures must reflect this. To ensure that only the most recent version of documents is available to staff members while they are doing their jobs, the QMS must limit document access. Documents that are no longer valid or necessary should be swiftly removed from all locations to avoid unintentional use. If papers are stored and shared electronically, read-only versions that can only be modified by authorized staff should be used.

16. Managing the 7 Ms in a laboratory

The scientific community has come to the consensus that scientific publications must be supported by solid scientific evidence collected in a setting where all variables that could affect the caliber of a finding are strictly controlled. The Ishikawa Fishbone diagram can be used to represent these factors, which can be broken down into seven main categories: Mother Nature (environment), Mother-Nature (environment), Manpower, Management, and Measurement. The adoption of a QMS that incorporates the seven Ms is an opportunity to guarantee the caliber of research findings as well as to advance and gain credit for the job done in a research laboratory.

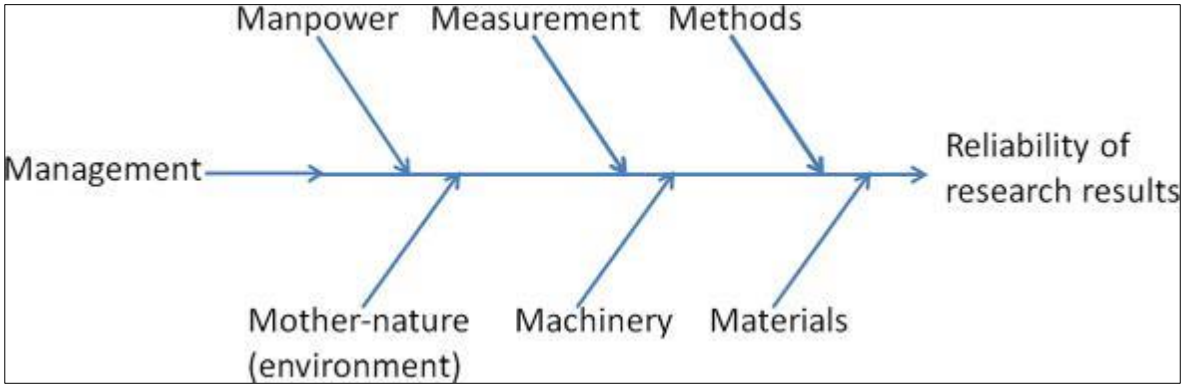

Figure 3 7 M's of Laboratory

16.1. Management and Manpower

The lab has decided to use a comprehensive quality management strategy that takes into account issues related to prevention and sustainable development. The Management Board decided on a participative management approach for the QMS's implementation in order to promote communication between teams and disciplines. It is crucial to pay attention to human resource management from the beginning in order to assure the validity of study findings. This entails determining the roles and abilities necessary (in terms of knowledge, skill, and experience), and subsequently the training needs, welcoming new hires, and maintaining records of initial and ongoing training.

16.2. Methods

Researchers must have at their disposal all the data that may affect test outcomes while analyzing test results. The formalization of methods is crucial as a result. This entails keeping track of every step of sample collection, measurement, apparatus analysis, kit lot numbers, sample identification, storage temperature, etc.

16.3. Machinery and Measurement

The management of equipment that must comply with regulations or is known to affect the caliber of research findings is under the preview of the laboratory. This gives it the authority to make sure that the proper procedures are followed for equipment purchase, maintenance, calibration, and verification.

Each selected critical equipment has a separate service-life file that allows for event tracing and maintenance, verification, and/or calibration monitoring. All previous results must be verified again when a piece of equipment fails

a conformity check. The standard equipment management and control methods, as well as the equipment user, maintenance, calibration, verification, and monitoring instructions, encompass all equipment-related processes. Critical equipment has been subject to annual internal and external verification according to a specified timetable.

16.4. Mother-nature and Materials

Identifying important factors that call for extra attention and indicate when samples need to be held at 80 °C. Pathogenic organisms (bacteria and fungi), seeds, leaves, twig fragments, fruit pieces, as well as DNA, RNA, and proteins are all kept in the lab. The need for an on-site power generator, the installation of -80 °C freezers in an air-conditioned room, the use of a monitoring system for each freezer and cool room to ensure dependability (for a backup -80 °C freezer, and the maintenance of freezers and cool rooms by an external company with a rapid response time) have all been identified as requirements to control the risks associated with inadequate cold storage conditions (at temperatures of -80 °C,- 20 °C.

17. Conclusion

A well-organized laboratory with distinct staff duties and an effective communication structure can be achieved by establishing standard operating procedures for technical assistance and laboratory administration. Adoption of the QMS results in improved internal control, a good tracking system for all laboratory activities, a solid infrastructure for tracking down errors and complaints, and an effective and controlled documentation system. The use of important quality indicators aids in the quick detection of system flaws and problem resolution. The implementation of standards also contributes to enhanced time savings and a decrease in operational costs. Increased worker proficiency is largely to blame for these cost savings.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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