

## **Training Module**

# **Management Requirements for a Laboratory Quality Management System**

**LABS FOR LIFE PROJECT**

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## Background

In health systems, outcomes greatly depend on the accuracy, reliability and timeliness of diagnostic services. Hitherto geared towards technical advances, the focus in medical laboratories in the last two decades has shifted to establishing quality systems for achieving these objectives.

The laboratory is a complex system, involving multiple operations, operators and locations of operation, that need to be performed competently and in a synchronized manner. Thus quality assurance in the laboratory requires both standardization and synchronization of various factors such as safe sample collection and transportation ensuring the safety of the operators & patients and integrity of the sample, optimum laboratory environment, adequate quality control procedures, effective communications, record keeping, competent, committed & skilled staff and adequate reagents and equipment that are fit for purpose and are stored and maintained well. It entails ensuring access to required resources and making the available resources functional through planning, training, rationalizing the workflow and error reduction. Moreover, adapting to changing demands of the highly dynamic modern diagnostic medicine requires continuous quality improvement which is possible only with long term vision and monitoring & evaluation to direct the laboratory towards this vision.

All these cannot be accomplished by frontline employees alone. Management's leadership and commitment are essential to guarantee the best outcomes. Thus establishment of Quality Management System (QMS) in the laboratories, to hold together the multiple components of management and technical responsibilities, is essential for good laboratory practice. Quality management helps in assuring conformance of the lab activities to the requirement of the user, reduces waste and leads to improved productivity. This in turn, reduces costs and provides a competitive advantage. QMS mandates that the upper level management support the frontline employees and empower them to identify and solve problems in their work processes.

There are International Standards that enable setting up laboratory Quality management System. ISO 15189 Medical laboratories — Requirements for Quality and Competence is one such standard that directs each activity to establish a Quality Management System. Other guidelines such as, CLSI (Clinical Laboratory Standardization Institute) also provides assistance in this regard. As compliance to the ISO standard begets accreditation in India, this module explains each concept as mandated by the ISO standard, with regard to management responsibilities in the establishment of Laboratory Quality Management System. The module navigates the reader through each management clause and sub-clause of the ISO standard. Effort has been made to align the flow of the concepts in accordance with the ISO clauses.

However, in some areas, rearrangements have been done to maintain flow. ISO clause numbers are given alongside, wherever warranted. Additionally, it may be noted that some of the ISO stipulated clauses have been discussed extensively as separate modules. In these situations, the reader has been referred to the respective modules. Narration along CLSI

standards are resorted to in some areas to enable more clarity. Samples of many formats required for the maintenance of the Quality Management System are included in the annexure.

## How to use this module

**Chapter 1:** describes the basic concepts about Laboratory Quality Management System in conformance to ISO 15189. It outlines the clauses as stipulated by the standard.

**Chapter 2:** talks about the organization and management responsibilities (ISO 15189 clause 4.1 and some aspects of clause 4.2). This will help learners to understand about legal and ethical issues in a medical laboratory, the importance of defining the organizational structure, interrelationships, expectation and management responsibilities in the laboratory's QMS.

*Since clause 4.3, 4.4 and many aspects of clause 4.2 are addressed through other training modules, these are not explained further. Lab for Life Project's training module on Documentation may be referred for clauses 4.2 & 4.3 and training module on Sample Collection & Pre-analytical Best Practices may be referred for clause 4.4*

**Chapter 3:** Ensuring that the referring labs are provided reports conforming to its Quality Policy can be done only if the referral lab's activities are understood fully. This chapter talks about the details of these as per ISO clauses, the difference between referral and referring laboratories and the requirements thereof. (ISO 15189: clause 4.5).

**Chapter 4:** External services and supplies refer to reagents, consumables, equipment; and services sourced in. To ensure the quality of these, several steps have to be assured. As details of these are addressed through other training modules, these are not explained further. (ISO 15189 clause 4.6). *Please refer to Equipment Management Module and Inventory Management Module for details.*

**Chapter 5:** It is the responsibility of the management that the potential users know and understand the scope of the laboratory's activities. It also is its responsibility to understand the needs of the users and make additional services available. All these aspects are discussed under the Advisory Services (ISO 15189 clause 4.7)

**Chapter 6:** Good laboratory practice warrants customer interactions. In such interactions lies tremendous scope for improvement. In this regard, the ISO include resolution of complaints (ISO 15189 clause 4.8) as an integral part of laboratory activities. Additionally, feedback is suggested (4.14) as a powerful tool for improvement.

**Chapter 7:** This chapter explains a series of concepts towards continual improvement as discussed in the standard under ISO 15189 clauses 4.9 – 4.12. Nonconformities that can occur in medical laboratories and the process for identification, handling and control of these, importance of corrective action, process for corrective action whenever nonconformity is detected, the concept the importance of continual improvement.



Since clause 4.13 is addressed through the training module on documentation this is not explained further.

**Chapter 8:** Evaluation of a quality system is very important. This is a continuous process in many respects but must include periodic, specific activities directed solely towards evaluation. This chapter describes the evaluation and audits (ISO 15189 clause 4.14): evaluation criteria for quality systems, definition, process and importance of audits, risk assessment, reviews by external organizations are explained.

**Chapter 9:** Management review is a valuable component of the quality management systems in accordance with ISO 15189. This chapter explains the methods and requirement of doing the same

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## Chapter 1 – Quality Management System

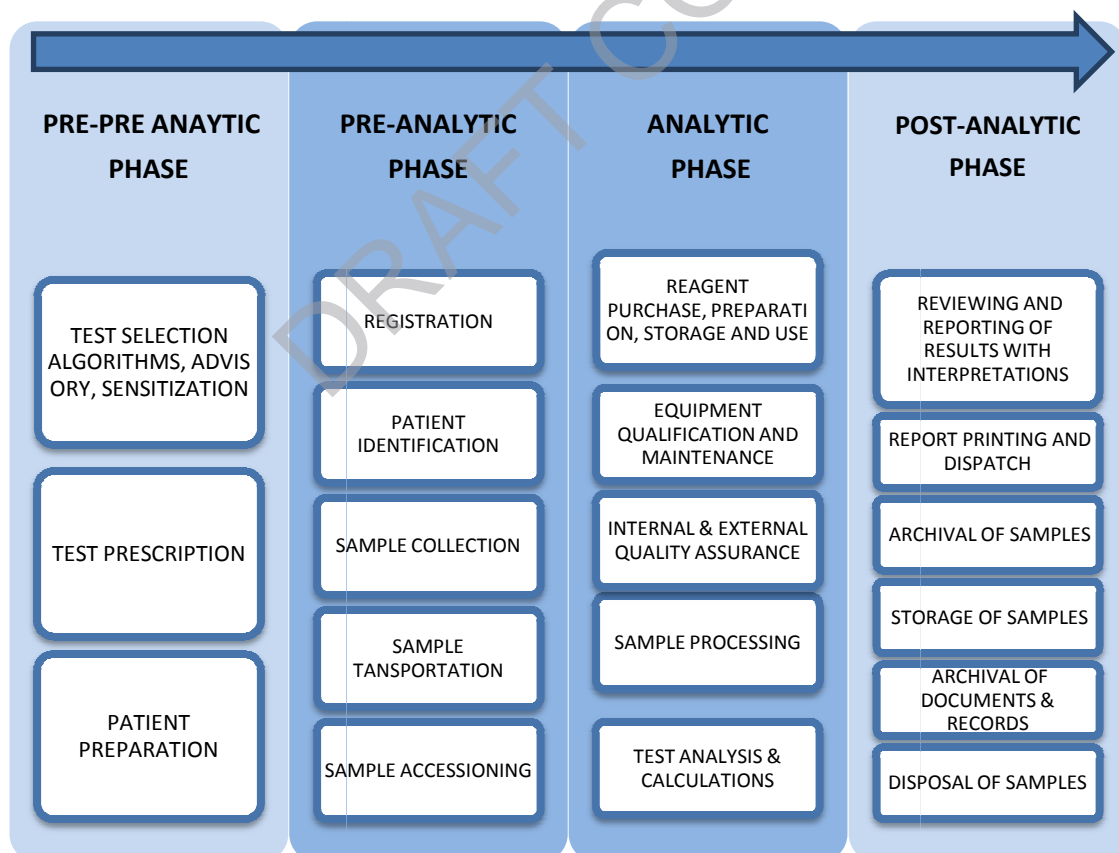
**Learning Objectives:** At the end of this chapter the reader will get an overview of -

- What is a Quality Management System
- What is ISO's role in laboratory QMS
- How is management responsible for running a lab effectively

### What is a Quality Management System?

A quality management system can be defined as “coordinated activities to direct and control an organization with regard to quality”.

To ensure the best patient care, quality and reliability in reports and confidence of users in the laboratory services, it is ideal to develop Quality Management Systems encompassing all functions of the laboratories. A medical laboratory comprises of a chain of various processes performed by different personnel at different locations. The diagram below throws light on this large concept in a simplified way.



*Figure 1: Process Workflow in a Laboratory*

Quality Management System integrates, standardizes and synchronises aspects of pre-pre analytic, pre-analytic (pre-examination), analytic (examination) and post-analytic (post-examination) phases of laboratory testing. Quality Management System (QMS) thus is an important tool to achieve good outcomes in laboratory performance consistently (Figure 1).

### **How does a Lab Establish a Standardized QMS?**

When a lab decides to set up a QMS in the lab, the question arises regarding how this can be done. A lab requires guidance in all aspects regarding the standard protocols available. Such standard protocols are available with prominent organisations viz. International Standardization Organisation (ISO 15189), Clinical Laboratory Standardization Institution (CLSI GP26). In India ISO 15189 is followed and National Accreditation Board for Testing and Calibration Laboratories (NABL) gives accreditation for compliance with the ISO standards.

In this module, the description of management requirements is from the ISO perspective. ISO 15189 draws its concepts from ISO 9001 and ISO 17025, with additional changes incorporated for clinical laboratories. The current issue of ISO 15189 is released in year 2012. Conformance to this standard is awarded by accreditation by NABL and other accreditation boards, in India.

### **How to Achieve Standardization of a Laboratory Using ISO 15189?**

**ISO 15189, “Medical laboratories — Requirements for quality and competence”** fulfils the requirement for both Quality and Competence, which are the essentials for reliability, accuracy and continued improvement in performance of a clinical laboratory.

#### **What is Quality?**

As per ISO definition **“quality is the degree to which a set of inherent characteristics fulfils requirements”**. This is demonstrated through documentation of the establishment, implementation and maintenance of the QMS.

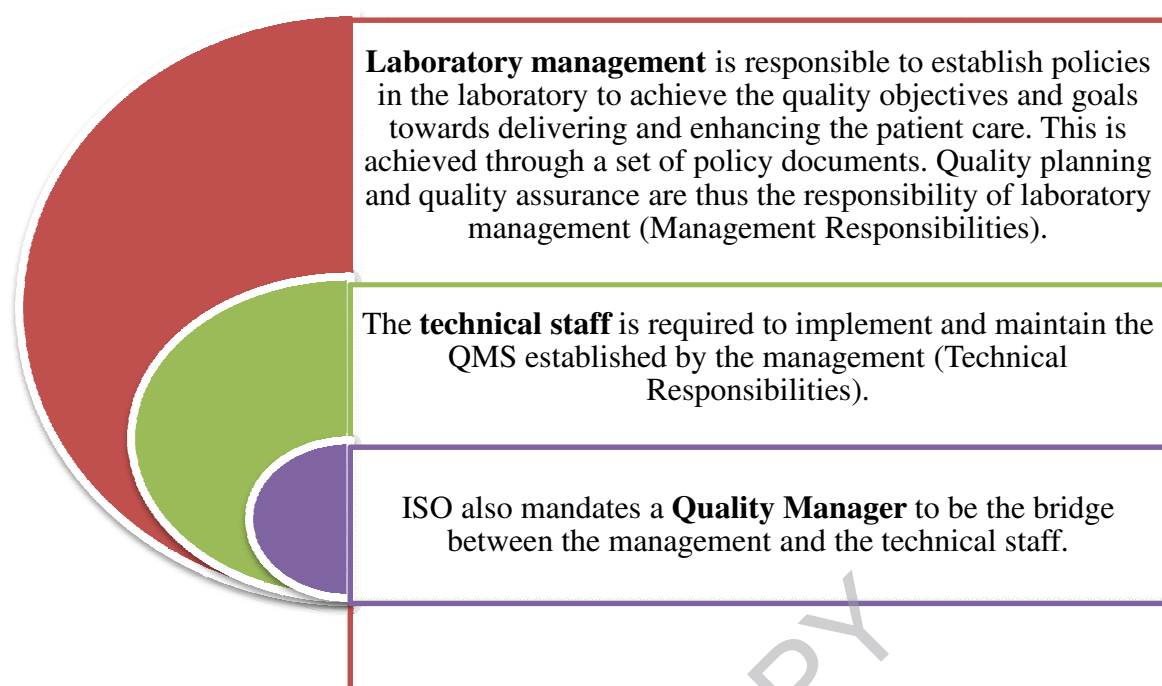
#### **What is Competence?**

As per ISO definition **“competence demonstrated ability to apply knowledge and skills”**. The laboratory is also required to demonstrate its competence through assays of Quality Control samples, repeat testing and split testing during the assessment process

### **How does ISO 15189 bring about standardization?**

Laboratories are traditionally perceived as exclusively technical areas and technical expertise is assumed to be sufficient to run laboratories well. However, laboratories are heavily dependent on the management support for all kinds of resources. Laboratory management allocates financial (operating and capital budget), physical (space, facilities, equipment and supplies) and human (technical and support staff) resources to deliver adequate laboratory services to the customers. The ISO 15189 facilitates interaction between management and technical teams through a series of systematically stated clauses.

## The ISO 15189 Standard: An Overview



ISO requires a stated Quality Policy by the management to pronounce its commitment to quality. It also requires the management to state Quality Objectives towards its goal for improvement. More about these are said in later sections. Management then should state its policies in all areas of laboratory activities to achieve the set quality policy and quality objectives. To ensure the sequence and interaction of multiple processes, as work flows in a laboratory, the ISO 15189 standard is divided into Management and Technical requirements; navigating the reader along the necessary activities.

The ISO 15189 standard incorporates 4 major clauses; the first 3 of which deal with the scope, references and glossary. Clauses 4 and 5 deal with the management and technical requirements, respectively. **Clause 4** deals with the establishment of a documented Quality Management System. It has 15 sub-clauses pertaining to management requirements. **Clause 5** stipulates technical aspects for implementing and maintaining the QMS established by the laboratory. It has 10 sub-clauses pertaining to technical requirements (Table 1). Each sub-clause has further sub-clauses.

*Table 1: Management and Technical QMS Requirements*

Clause 4	Management Requirements (Clause 4)	Clause 5	Technical Requirements (Clause 5)
<b>4.1</b>	Organization and Management responsibility	<b>5.1</b>	Personnel
<b>4.2</b>	Quality Management System	<b>5.2</b>	Accommodation and environmental conditions
<b>4.3</b>	Document control	<b>5.3</b>	Laboratory equipment reagents and consumables
<b>4.4</b>	Service agreements	<b>5.4</b>	Pre-examination processes
<b>4.5</b>	Examination by referral laboratories	<b>5.5</b>	Examination processes
<b>4.6</b>	External services and supplies	<b>5.6</b>	Ensuring the quality of examination results
<b>4.7</b>	Advisory services	<b>5.7</b>	Post examination processes
<b>4.8</b>	Resolution of complaints	<b>5.8</b>	Reporting of results
<b>4.9</b>	Identification and control of non-conformities	<b>5.9</b>	Release of results
<b>4.10</b>	Corrective action	<b>5.10</b>	Laboratory information management
<b>4.11</b>	Preventive action		
<b>4.12</b>	Continual improvement		
<b>4.13</b>	Control of records		
<b>4.14</b>	Internal audit		
<b>4.15</b>	Management review		

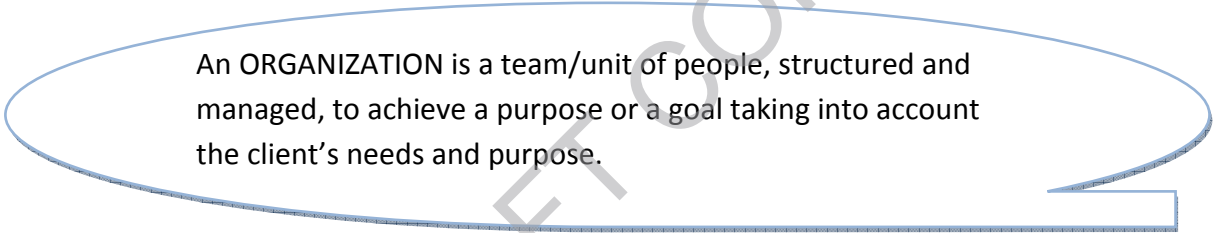
## Chapter 2: Organization and Management Responsibility (ISO 15189 Clause 4.1) & Quality Management System (ISO 15189 Clause 4.2)

**Learning Objectives:** At the end of this chapter, the learners should be able to understand the

- Concept of organizing the medical laboratory
- Legal and ethical issues in a medical laboratory
- Organizational structure -delineation of authority and responsibility, identification of hierarchy
- Role of Laboratory Director(s) and Quality Manager
- Management's role in the establishment, implementation and monitoring of QMS
- Importance of communication and training

In this chapter we will examine clause 4.1 and 4.2 with their sub clauses

### 2.1. Organization (4.1.1)



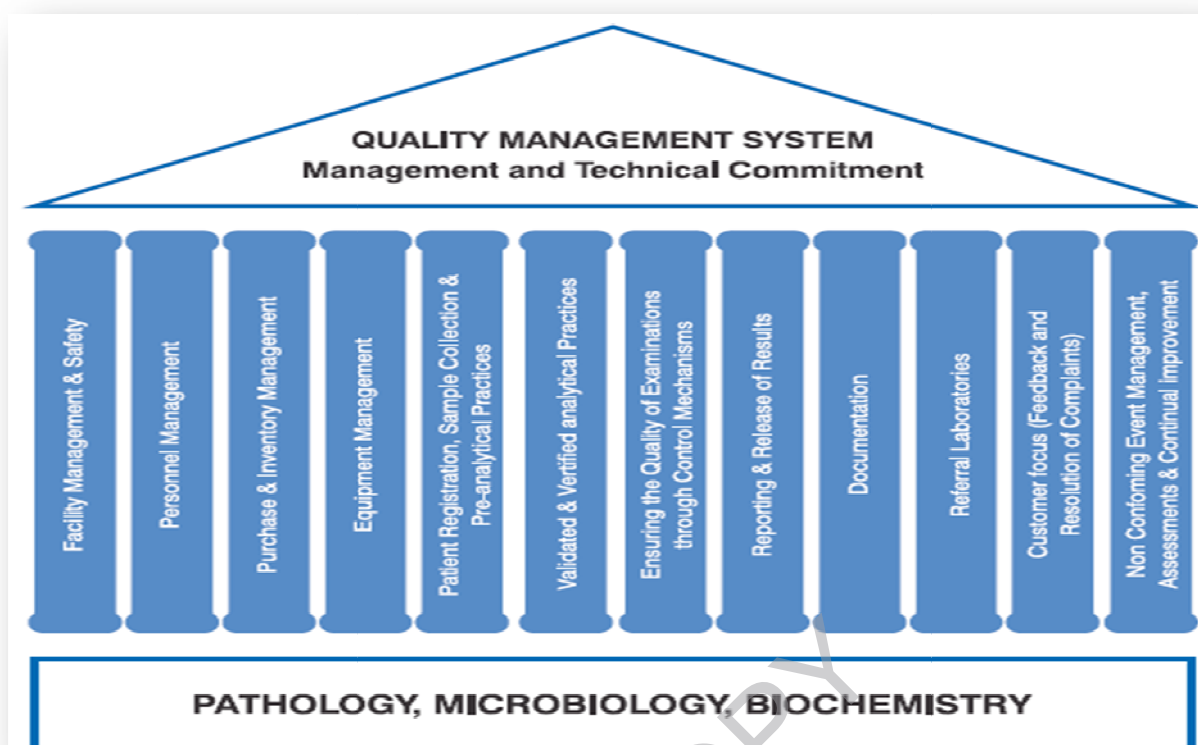
An ORGANIZATION is a team/unit of people, structured and managed, to achieve a purpose or a goal taking into account the client's needs and purpose.

ISO 9001 introduces the concept of QMS by defining organizational activities/processes, inter-relation between them and job descriptions of personnel responsible for each of them.

In developing a QMS;

- An overview of QMS requirements all along the sample path, described earlier, has to come into focus.
- Involvement of all levels of staff is essential. The relevant staff at different points must come into the planning, execution and maintenance of the QMS.

Thus the term “organization” indicates the management and the supporting organizational structure of the laboratory. Organization is one of the essential elements of the quality system which when coordinated with assigned responsibilities forms pillars of a quality management system(Figure 2).



*Figure 2: Elements of a Laboratory Quality Management System*

Let us now examine how to organize a laboratory as per ISO 15189 standard, going by the specific clauses. Each clause takes the reader into specific activities needed to ensure good laboratory practices.

#### 2.1.1. Legal Entity (ISO 15189: 4.1.1.2)

Legal entity is an association, corporation, partnership, proprietorship, trust, or an individual, that has legal standing in the eyes of law

#### **Need for legal entity**

A medical laboratory must produce relevant evidence of legal identification which can be any government notification in support of establishment of institution / laboratory or any approval from local or regulatory bodies

**All district hospitals are government concerns and may not require separate legal identities.**

#### **Compliance requirements**



- Laboratory should comply with local / regional / national requirements, as applicable. A few statutory compliances have been listed below:
  - No objection certificate from the Competent Fire Authority
  - Authorisation under Bio-medical Waste Management Rules, 2016
  - Clearance from State Pollution Control Board

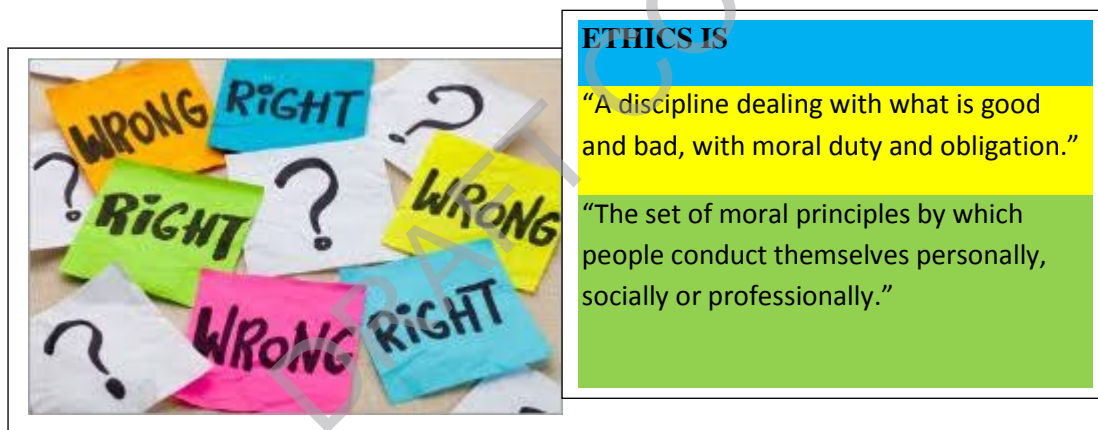
*Please refer to IPHS standard, Annexure 8, p.102, 'List of statutory compliances'*

- International standards specifies that the laboratory should clearly identify itself to the public, assuring that an identified person is in-charge and accessible.

*Note: The laboratory or the hospital/organization of which the laboratory is a part should be legally identifiable as per the existing law and authority. Every laboratory must at least make public, the laboratory's name and address, and the name of the director, including relevant contact information.*

#### 2.1.2. Ethical Conduct (ISO 15189: 4.1.1.3)

### WHAT IS ETHICS?



*Figure 3 Ethics*

The **principles** of doing "good" and not doing "harm" are the essence of every code of medical ethics and the same is applicable in medical laboratories. Principles that form fundamental in medical ethics are:

<b>Maintain Confidence in the Lab</b>	Competence, impartiality, integrity
<b>Maintain Confidentiality</b>	All patient information to be confidential
<b>Avoid Conflict of Interest</b>	Any competing interest must be declared
<b>Statutory compliances</b>	Treat human samples as per statutory requirements, comply with all regulations that apply
<b>Autonomy</b>	Right of patients to take decisions for themselves
<b>Beneficence</b>	Duty to act in the best interests of the patient
<b>Non-maleficence</b>	Duty to avoid any harm to the patient
<b>Justice</b>	Duty to remain fair and right

*Figure 4: Principles in Laboratory Ethics*

#### **Responsibility:**

Laboratory management holds the responsibility for supervision ethical conduct in the laboratory while it is the duty of all the lab personnel to follow ethical conduct during all the processes of the laboratory. Lab Director/Pathologist must ensure the same.

#### **How is it implemented?**



*Figure 5: No right way to do a wrong thing*

- Laboratory **should also be aware of situations** which could give rise to conflicts of interest and take particular care and should have **mechanisms to control** these. Declare the situations which may result in conflict of interests. The policy and process of third party testing or other subcontract activities should be well defined and listed.

- Ethics should become an important part of **induction training**
- Policies and processes should be made to **safeguard the confidentiality** of information related to patient sample and test results. **Undertaking of confidentiality** must be taken at the time of induction training. (*Annexure A: Confidentiality Undertaking; Sample*)
- Record of **patient's consent** must be maintained. (*Annexure B: Consent form; Sample*)
- Ensure authorized access to results.
- Standardization of system and work processes to ensure **impartial approach** in all activities
- Make adequate arrangements related to facility, workforce, finance or any other resources to refrain lab personnel from any financial, **commercial or any other pressure** which may affect the quality of the services provided by the laboratory.
- Handle patient samples (human samples, tissues or remains) as per specified **legal requirements**.
- **Work authorization** should be given and documented to all the personnel in their individual job descriptions. This should be a part of induction training. (*Annexure C: Job Description; Sample*)

*Note: Undefined or mixing of responsibilities for testing and quality creates internal conflicts of interest that are detrimental to quality. So, laboratory should have predefined responsibilities for all the lab personnel.*

#### **Examples of Breach of Confidentiality (What you should NOT do)**

##### **Accessing information that you do not need to know to do your job:**

- Unauthorized reading of patient account information
- Unauthorized reading of a patient's chart

##### **Sharing, copying or changing information without proper authorization:**

- Making unauthorized changes on a patient's chart
- Making unauthorized changes to an employee file
- Discussing Confidential Information in a public area such as a waiting room, elevator or cafeteria
- Posting a picture of a patient on social media.
- Emailing Confidential Information outside the institute/hospital by unsecure methods (not encrypted)

##### **Sharing your User ID and password: (for LIS equipped laboratories)**

- Telling someone your password so that he or she can log in to your work
- Giving someone the access codes for employee files or patient accounts
- Being away from your computer while you are logged into an application

### 2.1.3. Organizational Structure

As per the ISO, some major factors must be ensured with regard to organisation; (a) defining its structures with defined flow of authority, (b) stating each person's job descriptions clearly, (c) assigning lab director(s) and (d) a quality manager. We will look into each of these now.

#### **a. Defining of organizational structure (ISO 15189 Clause 4.1.2.5)**

The defining of organizational structure leads to efficient and effective laboratory operation and meeting the quality goals.

The organizational structure in a medical laboratory is explained ideally in the form of an organogram or an organizational chart depicting the designations, reporting relationship and hierarchy.

#### **Key Requirements:**

- Clear designation of authority, inter-relationships and responsibility at each level with an escalation matrix
- Accurate assessment of available personnel to perform different activities

#### **What is an organizational chart?**

An organizational chart depicts how jobs/tasks are divided, grouped and coordinated. Jobs are categorised into departments and departments are linked to frame an organizational structure. It is a line diagram that outlines an organizational structure and supports an optimal path of workflow. An organizational chart depends upon the goals, environment, technology and size. In addition, the organizational chart must also describe how the laboratory is positioned in the organization or its parent structures.

Organizational chart defines the working structure for the organization; organizes jobs along lines of authority; defines reporting structure and span of control; defines authority to make decisions and accountability for results; works together with job descriptions to define the working structure of the organization. (Laboratory Quality Management System Handbook, WHO)

#### **Why do we need an organizational chart?**

- For establishing core authority and responsibility
- For clarifying different authorities and responsibilities for the Laboratory Director/doctors, the Laboratory manager and the Technical supervisors and support staff (e.g. IT, Administration, HR, etc.)
- For identifying hierarchies and relationships
- For clarifying reporting lines
- For clarifying expectations

- For support the optimal path of workflow for the best possible quality outcome.
- For understanding the path of escalation of problem resolution

### How to make an Organizational Chart?

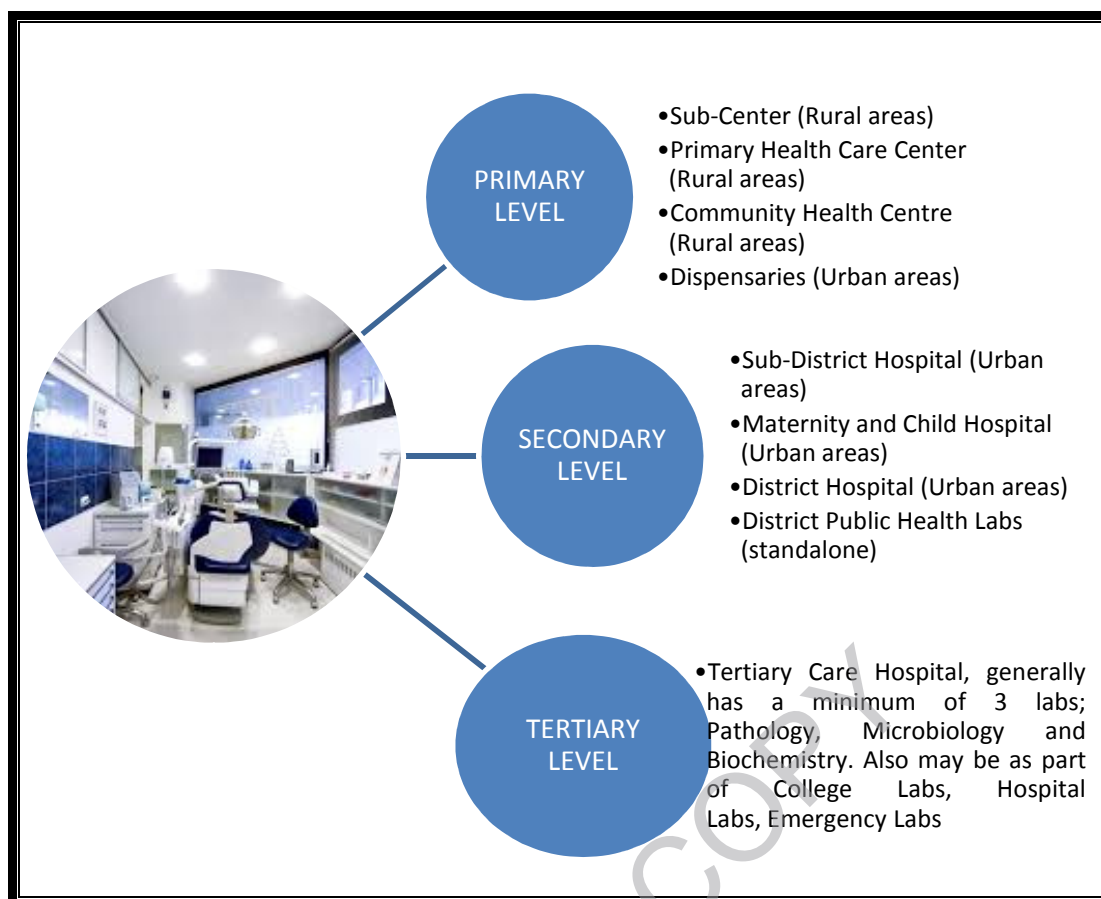
- For the laboratory which is part of a hospital/organization two types of Organizational Charts:
  1. One reflecting the place of laboratory within the total organization i.e., the relationship of the institution to the government structure.
  2. One showing the organization of positions i.e., hierarchy in the medical laboratory.
- List all the departments in the organization/laboratory and name of positions, as applicable.
- Arrange each separately describing their relation to other in hierarchy.
- Each chart must be reviewed and authorized by the person assigned for the same.

#### Note:

- *They are part of Quality Manual and must be accessible to all the lab personnel.*
- *Many errors can be prevented in the laboratory if the responsibilities of laboratory personnel are clearly defined and all staff members of laboratory understand what each is supposed to do and escalate to whom in case of some issue not getting adequate, timely resolution*

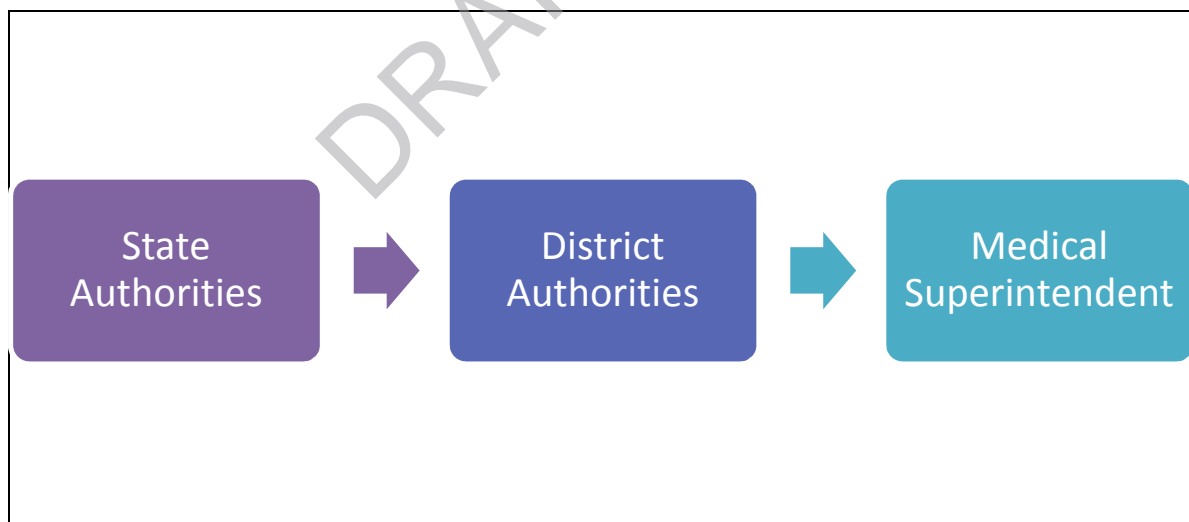
### Healthcare System in India

Public Health System in India consists of state owned hospitals under state government and few by the central government (Ministry of Health & Family Welfare). These facilities are further categorized as Government Medical Colleges (Tertiary), District Hospitals, Sub-district Hospitals, Community Health Centres (Secondary) and Primary Health Centres (Figure 6).



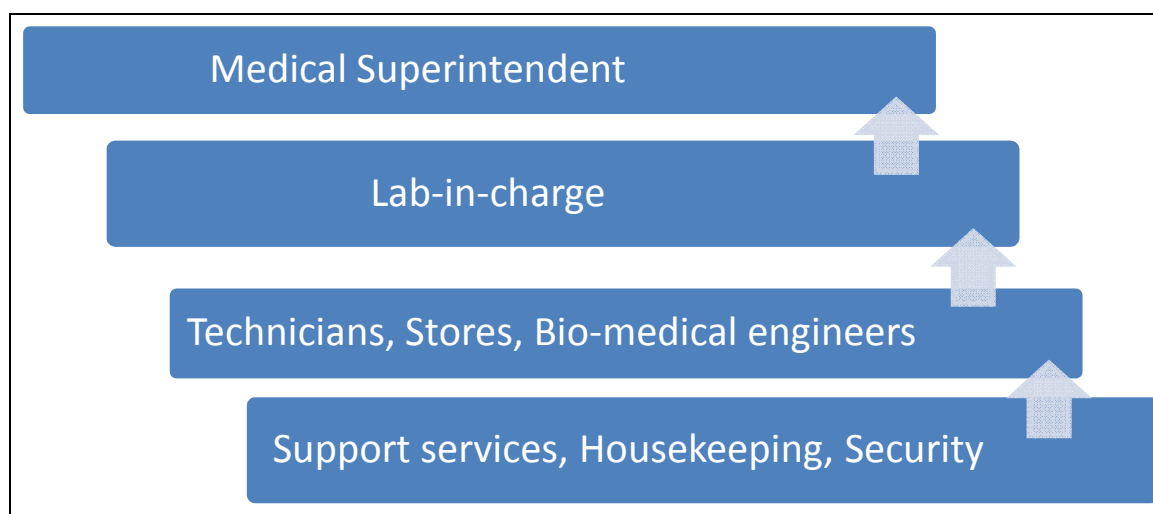
*Figure 6: Tiers of Indian Diagnostic Laboratories*

The organizational chart for higher management can be shown as below:



*Figure 7: Higher Management in a Laboratory*

The organizational chart (Figure 8) for Functional Management can be shown as below:



*Figure 8: Flow of Authority in a Laboratory*

Each of the above designations may be held by one or more people. All these must be depicted in the Organogram (*Annexure D: Organogram; Sample*)

- b. Job Descriptions:** A job description is a document that describes the general tasks, or functions, and responsibilities of a position. It may specify the functionary to whom the position reports, specifications such as the qualifications or skills needed by the person in the job. All expectations from that functionary should be clearly defined. Deputed work, emergency duties etc. should also be incorporated. This should be read and understood by the functionary and evidence towards this documented. Such undertakings must be done during the induction training of staff.

**c. Designating a Laboratory Director (ISO 15189: Clause 4.1.14)**

A LABORATORY DIRECTOR is person/persons who direct the laboratory with the competence and skills and delegated responsibility for the services.

OR

A LABORATORY DIRECTOR is person/persons responsible for all the activities and administration in the laboratory.

As the definition implies, the lab may be directed by more than one person. This is commonly observed in government institutional labs as the defined responsibilities and authorities are held by more than one person, ideally one each from the management and technical sides (designated co-directors). **The responsibilities assigned should be consistent with the authorities given to the person.** Howsoever the responsibilities are assigned; it should be documented and evidenced.

## Responsibilities of Lab Director:

*Table 2: Responsibilities of Lab Director(s)*

Nature of responsibility	Activities	Suggested co-directors
Professional and Scientific:	<ul style="list-style-type: none"><li>• Clinical interpretation of the clinical laboratory data.</li><li>• Communicate effectively in interpreting clinical results to the referring physicians or care provider or as applicable.</li><li>• Monitor all the processes performed in the laboratory to ascertain on time patient care, quality and reliability of services provided by the laboratory.</li><li>• Preparation of Quality System Processes in consultation with the Technical Managers.</li></ul>	HOD/Lab in-charge
Consultative/Advisory:	<ul style="list-style-type: none"><li>• Provide consultation to physicians regarding the medical significance and interpretation of disparate laboratory findings.</li><li>• Recommend or advise additional test to clinically ascertain the diagnosis of the disease.</li></ul>	HOD/Lab in-charge
Organizational:	<ul style="list-style-type: none"><li>• Designing, approval, implementation and maintaining of the quality management system.</li><li>• Involvement in preparation of policy documents along with the higher management.</li><li>• Stating the quality policy.</li><li>• Ensure that the laboratory develops, implements, and maintains a quality system approach to laboratory testing to ensure accurate and reliable patient test results.</li><li>• Ensure that the lab follow safe work environment &amp; meet State, Regulatory and Accreditation requirements, whichever is applicable.</li></ul>	Dean/Principal/ Medical Superintendent/ PMO/CMO
Administrative:	<ul style="list-style-type: none"><li>• Participation in all managerial decisions and guides the daily operation of the laboratory, ranging from selection of staff, choice of methods, purchase of equipment, quality assurance, quality control, safety in compliance with good practice and scheduling of staff.</li><li>• Help in defining, implementing and monitoring</li></ul>	Dean/Principal/ Medical Superintendent/ PMO/CMO



	<p>the accepted standards of performance in quality control, quality assurance, and cost-effectiveness of the laboratory service.</p> <ul style="list-style-type: none"> <li>• Assure that the laboratory participates effectively in required quality management programs.</li> <li>• Personally demonstrate leadership for the staff as they function as an integrated team. Leadership is important to optimize services to achieve the desired health outcomes for patients.</li> </ul>	
Educational:	<ul style="list-style-type: none"> <li>• Ascertain that all the procedures and tests performed by the medical and technical staff are within the scope of education, training, and experience of the individual.</li> <li>• Provide or arrange the trainings to the lab personnel regarding procedures and tests regularly.</li> <li>• Develop opportunities for laboratory staff to participate in continuing education programs.</li> </ul>	HOD/Lab in-charge

In addition to the above stated responsibilities, the director(s) should also

- Have defined deputies to whom the selected duties/responsibilities may be delegated. This person(s) also should possess the same competence as stated in the table. Such deputations should be clearly defined in their job descriptions (5.1.3)
- Be able to relate and function effectively with applicable accreditation and regulatory agencies, the medical community, and the patient population served.

*Note: The duties and responsibilities of the Laboratory Director should be documented under his/her Job Description.*

**d. Designating a Quality Manager (ISO15189: Clause 4.1.2.7)**

The Quality Manager is the bridge between the management and the technical teams. Therefore, he/she must be invested with the authority for the defined role and accessibility to both sides. In a QMS, the Quality Manager holds a very key role and should be accorded due importance. The robustness of the lab's QMS is heavily dependent on the commitment of the Quality Manager and the support he/she receives from both sides.

Therefore, lab management should appoint/designate a quality manager with delegated responsibility and authority to oversee compliance with the requirements of the quality management system and reporting directly to the level of laboratory management.

Quality Manager plays a key role in creation of QMS, spreading awareness amongst staff on the quality policy and quality objectives, to make them familiar with the processes used to achieve compliance with quality requirements.

Requirements for Quality Manager Quality Manager (as per NABL 112):

Designee shall be trained in 4-days Quality Management as per ISO 15189. She / He should be a full time employee, and can be delegated with additional responsibilities

**Responsibilities of Quality Manager (as per ISO 15189):**

- Ensuring that processes needed for the quality management system are established, implemented and maintained. e.g. ensuring that all levels of documentation are duly completed and updated
- Reporting to laboratory management at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement. e.g. ensuring that all challenges are identified, communicated to the management and followed up as quality objectives towards improvement
- Ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organization. e.g. opening channels of communication with the clinicians and users
- Conducting management review. E.g. regular updating of all stakeholders with documentation. It will be his/her responsibility to ensure that the meeting takes place, to minute the meeting, identify the corrective action required, set timelines for these and ensure compliance.
- Ensuring that all personnel are competent their assigned activities e.g. ensuring correct observance of job descriptions

**2.2. Need for Management Commitment (4.1.2.1)**

**Implementation of quality management system requires resources, facilities and review processes for continuous improvement which is only possible through commitment from management.** Only with coordination between management and technical staff in the organization can QMS be supported and implemented in the laboratory.

- Laboratory management should be committed to provide **necessary qualified and competent human and financial resource along with infrastructure facilities** to maintain laboratory quality management system as per ISO 15189.
- Management participation should **be visible**. This can happen through management review meetings (MRM), interaction with staff, sharing customer expectations, rewarding staff good performance, etc.

- Management also designates/ recruits key personnel that ensure adherence to the requirements and implementation of QMS like **Quality Manager and Laboratory Director**.



**Direct participation by the highest level management in specific and critical activities like facility management, safety, quality, environment, resources, etc. of an organization.**

### **MANAGEMENT COMMITMENT**

“Management Commitment” is the primary and essential element for successful establishment, implementation and monitoring of Quality Management System. The top or senior management must accept the responsibility and involve themselves in the establishment and maintenance of quality system in the laboratory. Management must visibly demonstrate and communicate this commitment.

*Note: Quality manual, quality policy, procedures and records required by International Standards and management reviews demonstrate management commitment to quality for meeting QMS requirements.*

#### **2.2.1. Essential Components of QMS Establishment under the Purview of Management:**

Though we are essentially following the ISO, at this juncture, it will be good to look at the CLSI guidelines about QMS. As per CLSI, there are 12 Quality System Elements (QSEs) that come under the purview of the management. All these are applicable along the sample path. These are organization, Customer Focus, Facilities and Safety, Personnel, Purchasing and Inventory, Equipment Management, process Management, Documents and Records, Information Management, Non-conforming event management, Assessments and Continual Improvement.

A few of these concepts along with other requirements are explained below aligning them to the ISO. The other points are explained in later chapters.

- **Understanding and Meeting the needs of users:(ISO 15189 Clause 4.1.2.2, Clause 4.7)**

- Laboratory management must ensure arrangements for best laboratory services along with appropriate advisory and interpretive services for fulfilling the needs and requirements of patients / users
  - Ensure that the lab meets the requirements of regulation and accreditation.
  - The same should be communicated effectively to the laboratory personnel for better understanding of support and efforts being taken by the management.
- **Expressing the Commitment towards Quality through Formulating and Establishing Quality Policy: (ISO 15189 Clause 4.1.2.3)**  
 Laboratory management is responsible for defining the quality policy of the laboratory. The quality policy is the mission statement and expresses the intent of the management to establish a QMS. This should:
    - Be appropriate to the services provided by the laboratory.
    - Include commitment to good professional practice, quality of examinations, complies with the International Standard and continual improvement of the quality of laboratory services.
    - Provide a framework for establishing and reviewing quality objectives.
    - Be communicated and understood within the organization.
    - Be reviewed for continuing suitability.
  - **Ensuring Continual Improvement through Quality Objectives (ISO 15189 Clause 4.1.2.4)**
    - Laboratory management should identify the challenges in the working of the lab and set measurable objectives
    - These must be consistent with the quality policy.
    - Quality indicators should be set for all objectives as per requirement to enable measurement of progress.
    - Quality objectives and indicators should be defined in consensus with all levels of lab staff. Improvements or the lack thereof should be regularly communicated.
  - **Defining Responsibility, Authority and Interrelations:(ISO 15189 Clause 4.1.2.5)**  
 As described previously, the laboratory management should define and document job responsibilities, authorities and interrelationships of all the personnel for each laboratory function. If required, deputies should be appointed for key managerial and technical personnel.

*Please refer to 2.1.3 of this module for details*

- **Communication:(ISO 15189 Clause 4.1.2.6)**

Management should also ensure that:

- Laboratory should have intra and inter departmental (other laboratories and clinical) meetings in a calendared manner. E.g. HICCs, Mortality Meets, CPC meets, etc. Minutes of all these meetings should be kept.

- Laboratory should communicate with the management in a calendared and as and when basis for better convergence.
- Lab management should establish means and processes for effective and timely communication with others viz. patients, regulatory bodies (L forms to IDSP, notifications of vector borne diseases to NVBDCP, HIV notifications to SACS, BMW specifics as per 2016 rules to Pollution Control Boards) and Accreditation & Certification bodies (NABL, SQAC of NHM).
- These communications should be in regard to the effectiveness of the laboratory's pre-examination, examination and post-examination processes and quality management system.
- Communication can be through emails, circulars, notices or through meetings (record of minutes of meeting).
- Records should be maintained of points discussed in communications and meetings.

- **Conducting Management Reviews: (ISO 15189 4.15)**

Laboratory management must conduct periodic reviews at least once a year to examine the suitability and effectiveness of the current established quality system in the laboratory. It helps to anticipate potential process failures, compliance deficiencies, regulatory deviations and areas of quality improvement. Any necessary changes in the policy, objectives and quality system from the outcome of the reviews should be implemented and documented. More about this is said in later sections.

- **Training (ISO 15189 Clause 5.1.5)**

Lab management, in coordination with the technical teams, should ensure adequate and regular trainings of all personnel and ensuring that the person designated for the process possess knowledge and competency to perform his or her duties. The training areas should include at least the quality management system, assigned work processes and procedures, the applicable laboratory information system, health and safety, including the prevention or containment of the effects of adverse incidents, ethics and confidentiality of patient information. A calendar for training has to be prepared and followed.

Personnel that are undergoing training must be supervised at all times and the effectiveness periodically reviewed. A sample calendar is shown below

*Table 3: Sample Training Calendar*

Training Calendar for Year 2017				
Topic	No: Proposed	Proposed Month/(s)	Responsibility	Status
Quality management system	8	Jan/March/May/June/July/Sept/ Nov/ Dec	Dr XYZ	3
Assigned work processes	6	Feb/April/June/Aug/ Oct/ Dec	Dr ABC	2
Laboratory information system	4	Jan/ July/ Sept/ Dec	Mr DEF	2
Health and safety	4	Feb/April/ July/ Dec	Dr LMN	1
Ethics	1	March	Dr PQR	
Confidentiality	1	July	Dr PQR	

- **Resource Allocation**

Lab management should ensure adequate and appropriate resource allocation for the proper conduct of pre-examination, examination and post-examination processes. These must include:

- Appropriate accommodation and environment
- Adequate human resources at all levels of technical functioning including technical supervisory staff, lab technicians, lab attendants, housekeeping and security
- Equipment availability and calibrations
- Regular supply of reagents and consumables
- Evaluating the resource utilization

## Chapter 3 - Examination by Referral Laboratories (ISO15189 Clause 4.5)

**Learning Objectives:** At the end of this chapter, the learners should be able to understand the

- Difference between referral and referring laboratory
- Process for selection and evaluation of referral laboratories
- Reporting of referral laboratory results

**Referral laboratory is an external laboratory to which a sample or sub-sample is submitted for a supplementary or confirmatory examination and is considered to have a similar or preferably better quality system.**

**Referring laboratory is a laboratory that submits samples or sub-samples for supplementary or confirmatory test, or when routine examination could not be carried out (e.g. due to equipment breakdown) and receives the report from the referral laboratory**

**Test not performed routinely by the laboratory are outsourced. This does not come under the ambit of Referral laboratory as per the ISO 15189 standard. However, these tests must also be diligently monitored.**

**Referral system here implies sample referrals and not patient referrals. Currently, in the public health system, patient referrals are the practice followed.**

**Under the following situations samples/consultation can be referred:**

- Instrument breakdown or reagents not available
- Workload restrictions
- Client requested turnaround time cannot be met
- To seek a second opinion
- To seek opinion during absence of authorized signatory in the laboratory
- As part of the Proficiency Testing mechanisms

Referral laboratories and consultants shall be selected as per the criteria laid down by the laboratory.

**Some suggested criteria for referral laboratories:**

- Accuracy and quality of results/consultations
- Meets facility and equipment requirements
- Uses verified testing and examination methods

- Compliance to Safety requirements
- Employs qualified personnel
- Accredited under ISO15189
- Has documented QMS
- Follows QC practices
- Acceptable performance in proficiency testing
- Effective turnaround time
- Provides timely advisory services
- Passes on-site inspection
- No conflict of interests

Arrangements with referral laboratories and consultants must be reviewed and evaluated periodically to ensure that the relevant parts of the International Standard are met. In cases, where the correct interpretation and application of examination results needs collaboration between clinicians and specialists from both referring and referral laboratories, this process should not be hindered by commercial or financial considerations.

#### **Documents required:**

- The referring laboratory should have a documented procedure (QSP) for selecting and evaluating referral laboratories and consultants who provide opinions as well as interpretation for complex testing in any discipline. (*Annexure E : Format for selection and evaluation of referral laboratories; Sample*)
- Record of approvals with signature on agreement/MoU should be preserved.
- A list of approved laboratories and approved consultants should be maintained.
- Record of reviews of arrangements and periodic evaluation with referral laboratories and consultants should be maintained.
- Records of all the samples referred, date of referral, name of person referring and to which referral laboratory/consultant should be maintained.
- Referring laboratory should standardize the procedure for reporting referral laboratory results considering turnaround times, measurement of accuracy, transcription, interpretative skill requirements.
- When the referring laboratory prepares the report, it replace include all essential elements of the results reported by the referral laboratory or consultant, without alterations that could affect clinical interpretation. The report replace indicate which examinations were performed by a referral laboratory or consultant. The author of any additional remarks replace be clearly identified in the report.
- Record or the photocopies of test reports are maintained.



## Chapter 4 - External Services and Supplies (4.6)

**Learning Objectives:** At the end of this chapter, the learners should be able to understand the

- Process for selection and evaluation of suppliers
- Documentation requirements

Any interruption in testing/services can affect patient care and management. Each laboratory should maintain sufficient and uninterrupted supplies and services to fulfil the needs of the clients and prevent wastage.

The supplies can be categorized as equipment, consumables, reagents and kits. The services include warranty/guarantee, maintenance contracts, attending to breakdowns (remote or on site) and calibrations.

The laboratory should select and approve suppliers based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory's requirements; however, it may be necessary to collaborate with other organizational departments or functions to fulfil this requirement.

Though this is a management requirement, technical inputs are critical to ensure quality assurance in this aspect of lab operations. *For details on equipment purchase, please refer under Design Qualifications in the Equipment Management module.*

As for reagents, the claimed Performance Characteristics as per manufacturer should be checked and approved by the technical team before selections are made. Pre purchase verifications for “fitness of purpose” are also possible before purchase if the manufacturer supplies adequate Performance Characteristics like coefficient of variation (CV), sensitivity and specificity, etc. Ideally, any financial bid should happen only after technical clearance. *For details on reagent purchase, please refer under Inventory Management Module*

**Both Management and Technical teams are equally accountable for the procurement of External services and supplies**

**Documentation required for process of selection, evaluation and implementation of external services and supplies:**

- The laboratory should have a documented procedure for the selection and purchasing of external services, equipment, reagents and consumable supplies that affect the quality of its services. Purchasing information should describe the requirements for the product or service to be purchased.

- Criteria for selection of suppliers should be established and documented. Some of the suggested criteria are –
  - Equipment - warranty, AMC/CMC, Remote/onsite support service, downtime, etc.
  - Reagent – maintenance of cold chain, long expiry, supply of steady lots, etc.  
(Annexure F1 :Format for Equipment supplier selection and evaluation, Annexure F2 : Format for Reagent supplier selection and evaluation; Samples)
- A current list of selected and approved of equipment, reagents and consumables should be maintained.
- The laboratory should monitor the performance and evaluate the suppliers to ensure that purchased services or items consistently meet the stated criteria. Laboratory should maintain the records of the same.

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## Chapter 5 - Advisory Services (4.7)

**Learning Objectives:** At the end of this chapter, the learners should be able to understand the

- Overview of advisory services in medical laboratory
- Documentation requirements

**What is an advisory service in a medical laboratory?**



An advisory service can be defined as a clinical laboratory consulting service about the appropriate use of clinical laboratory examinations (interval between sample collections, indications of examination, obsolete examinations, supplementary examinations, etc.), advice on clinical cases, logistic issues and the clinical meaning of examination results (interpretative comments).

Laboratory management should ensure that the following arrangements/processes are in place and confirm their implementation by the technical team

- Advising clients on choice of examinations (mainly outpatients where there is no doctor's consultation) and use of the services, including required type of sample, collection requirements, clinical indications, and limitations of examination procedures and the frequency of requesting the examination.
- Advising on individual clinical cases and need for specific confirmatory/additional testing
- Immediate communication of critical values
- Professional judgements on the interpretation of the results of examinations
- Promoting the effective utilization of laboratory services
- Consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria.
- Trainings/meetings between clinical staff and professional staff on the use of laboratory services and clinical interpretations.
- Hospital-attached laboratory personnel are encouraged to participate in clinical rounds and meetings.

**Documentation required:**

- Procedure for defining areas and implementation of advisory services.
- A list of critical (alert) values readily available to laboratory staff.
- Records containing notifications of critical (alert) values
- Records containing requests of advisory service (received and answered)
- An interpretive comment in every clinical laboratory report containing any laboratory examination.
- Records of client feedback, suggestions and satisfaction surveys should be maintained.
- Records of clinical rounds undertaken by laboratory personnel.

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## Chapter 6 - Resolution of Complaints (4.8)

**Learning Objectives:** At the end of this chapter, the learners should be able to understand the

- About the complaints in medical laboratory
- Process of resolution of complaints

### What are complaints?

Complaints are objections, negative feedbacks, errors, or non-conformities involving work quality, or failures to provide service or other requests of the users of the laboratory services including timeliness.

The idea of quality, accurate and reliable laboratory services can be evaluated on the basis of client satisfaction scores. Feedbacks from users of laboratory services covering key aspects can be taken periodically and reviewed for improvements. Complaints are included as a quality indicator in QMS of the laboratory for improvement of laboratory services, to avoid errors in future and ensure client satisfaction. Complaints in the medical laboratory can be received in writing, through emails, telephone, in person, on website or as feedback.

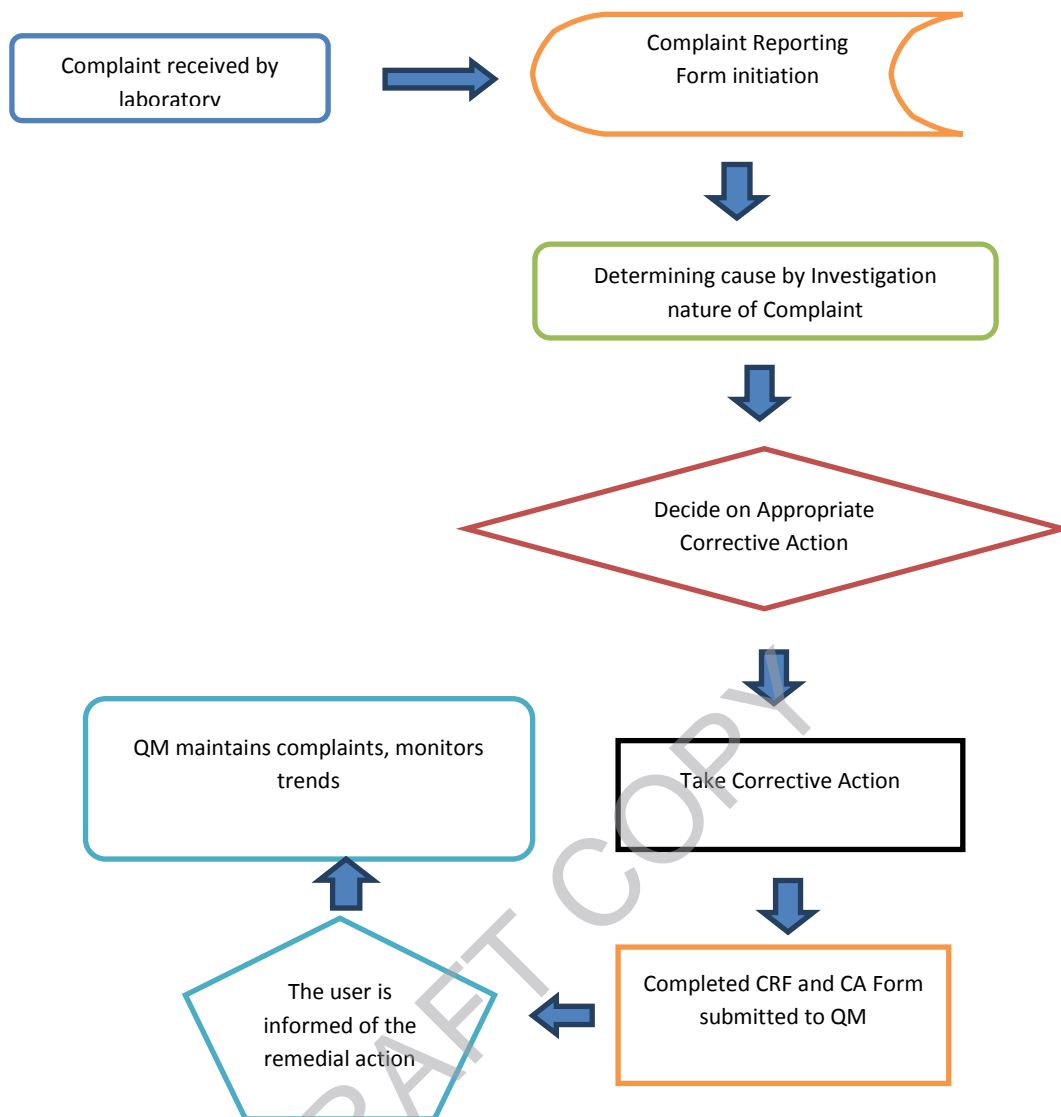
Laboratory management is responsible for ensuring the implementation of the complaint procedure and facilitates process changes, if required. Laboratory supervisors are responsible for recording complaints received on the complaint form and initiating corrective action in consultation with Lab Director. The Quality Manager monitors the comments and complaints received for trends, resolutions and corrective action. Every complaint should be taken to its logical conclusion of ascertaining that the client who made the complaint is satisfied with the remedial action taken; hence the title “resolution” of complaints.

*Note: Feedback, on the other hand, are information about reactions to the performance and services of the laboratory which can be used as a basis for improvement. Whereas complaints are negative in nature, feedback can either be negative or positive.)*

*(Annexure G: Format for feedback & complaint resolution; Sample)*

### Resolution of complaints; some salient points:

- The laboratory must have a documented procedure for the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties.
- The process of redressal should include receiving, reviewing, investigating the cause, corrective action taken and closure.
- The laboratory should maintain a record of all the complaints received and their investigation and action taken.
- The laboratory should have a complaint/feedback form to document each complaint and its redressal.



*Figure 9: Complaint Resolution Process Flowchart*

*Note: The laboratory should follow the existing corrective action and preventive action process in the laboratory during the resolution of complaints.*

## Chapter 7 –Improvement Process (ISO 15189 4.9 – 4.12)

**Learning Objectives:** At the end of this chapter, the learners should be able to understand the meaning of the following

- Nonconformities in Medical Laboratory
- Process for Identification, Handling and Control of Nonconformities
- Importance of Corrective Action
- Process for Corrective Action Whenever Nonconformity is detected.
- Concept and Application of Preventive Action
- Process for Implementation of Preventive Action
- Concept and Importance of Continual Improvement
- Processes in Laboratory to Ensure Continual Improvement
- 

This section deals with 4 clauses of ISO 15189; from 4.9 to 4.12

### 7.1 Identification and Control of Nonconformities (4.9)

**Conformity:** When the actual practices followed in the laboratory or the findings are in concordance with the laboratory's policies or the standard guidelines.

**Non-conformity:** Failure to fulfil the requirements of a specified process, structure or service. May be categorized as major (complete) or minor (partial).

Any nonconformity in a medical laboratory raises a question on the effectiveness of lab quality system or laboratory processes. Laboratory management must establish an effective and continuous process to detect all the Non-Conforming Events (NCEs) or else they will remain undetected.

Any nonconformity in performance implies that the policies and procedures set by the laboratory require revision or are not being followed. Nonconformities may arise during routine laboratory process, clinician complaints, internal and external audit, staff comments, customer feedback, laboratory indicators, PT/EQAS failures or management review (Refer Figure 10).

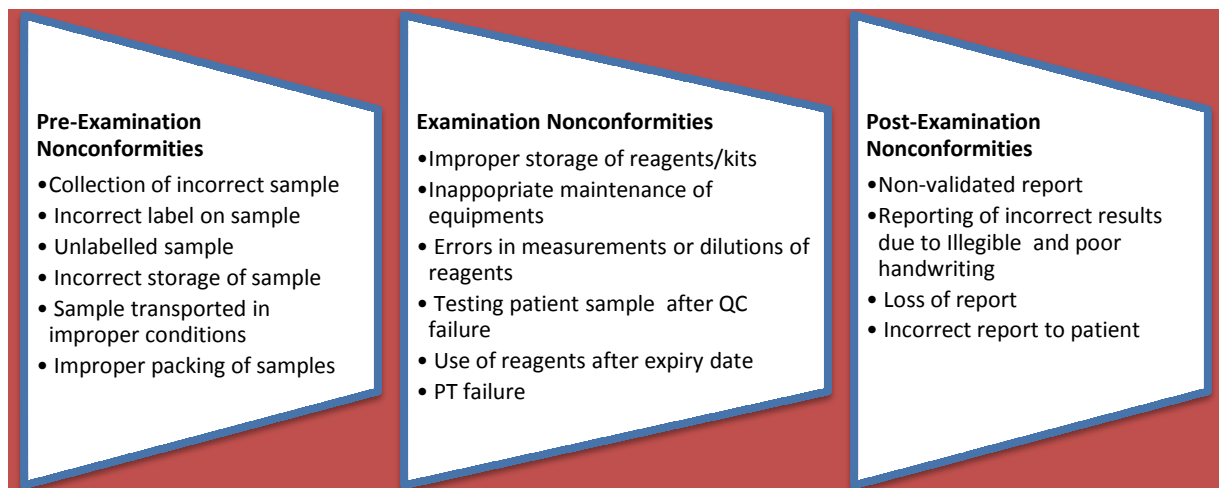


Figure 10: Few Examples of Nonconformities

The laboratory nonconformities may lead to the risk of

- Inadequate or inappropriate patient care
- Repetition of laboratory results
- More invasive testing
- Inappropriate public health action
- Undetected communicable disease outbreaks (in some cases)
- Wastage of resources
- Increased cost to patients and healthcare systems
- Even death of an individual.

Identification of nonconformities and appropriate corrective action aids in continual improvement of laboratory services.

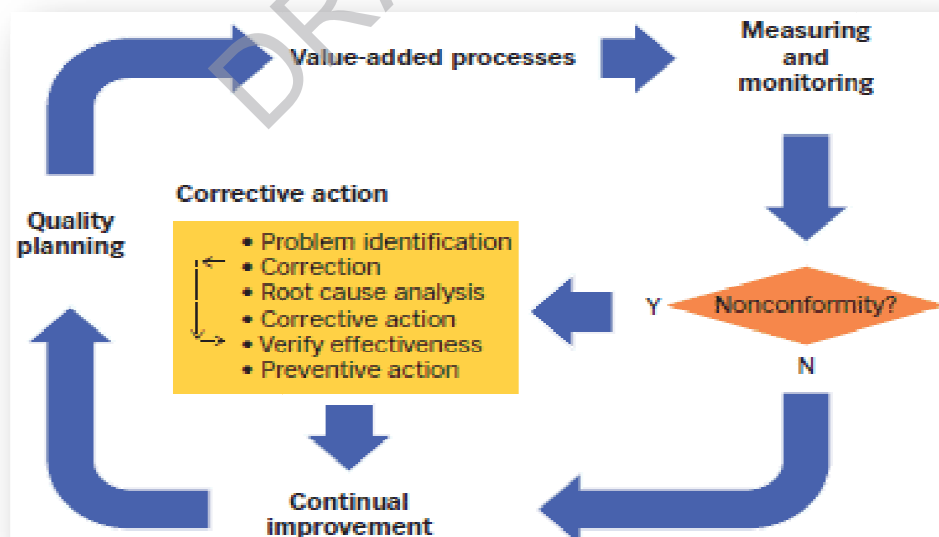


Figure 11: Management of Non-conformities



### Documentation requirements:

- The laboratory should have a documented procedure (QSP) to identify and manage nonconformities (occurrences) in any aspect of quality system, including pre-examination, examination and post-examination processes. This QSP may be extended to include sub-clauses 4.10 (corrective action), 4.11 (preventive action) and 4.12 (continual improvement) as well.

Responsibilities and definitions of responsibilities for handling NCEs are very important in every lab and thus these should be clearly defined.

- The responsibilities and authorities for handling nonconformities should be designated to appropriate personnel by the Quality Manager. (Though the responsibility for monitoring for nonconformities belongs to everyone in the laboratory)
- The cases when testing procedures and data reporting will be withheld due to nonconformities should be well-defined and when, and under what conditions, the examinations can be resumed should be specified.
- The steps that should be taken when the result of any nonconforming or potentially nonconforming examinations already released are recalled or appropriately identified, as necessary also should be defined.
- The responsibility for authorization of the resumption of examinations is defined.
- Each episode of nonconformity should be
  - Documented, recorded
  - Extent of non-conformity is determined
  - Immediate action: contain damage
  - Root Cause Analysis (RCA) is performed
  - Corrective Action: prevent recurrence
  - Results of the corrective action and its effectiveness is documented
  - Preventive Action: prevent similar occurrence
  - All supporting evidence for all the steps to be retained
  - All the nonconformities should be logged and recorded and these should be reviewed at regular time intervals to detect trends and initiate corrective action.

*(Annexure H: Format for NCE/Incident/ Occurrence/Accident reporting and immediate, corrective and preventive action taken; Sample)*

### *Note:*

- *Corrective actions taken should be appropriate to the non-conformities encountered.*
- *Records of nonconformities must be communicated to the lab management and form a subject of management review.*
- *Repeated non-conformities in the same area should be set as quality objective*

## 7.2 Corrective Action (4.10)

### Difference between remedial/immediate action and corrective action:

Immediate action is an action taken at the time of nonconformity, to mitigate its immediate effects. For example, if an erroneous result has been reported, it is essential to immediately notify all persons concerned about this error and withdraw the report. Corrective action would be to provide the amended result.

Corrective action is an action taken to eliminate the detected nonconformity or other undesirable situation (and the cause of it). As an example, a piece of equipment may have been malfunctioning, and the corrective actions would be to recalibrate, repair or otherwise address the equipment problem.

### Benefits of Corrective Action:

- To prevent recurrence of the problem
- To initiate quality improvement

Laboratory management should develop a quality system wherein, the process for identification of a nonconformity/occurrence/error, followed by a prompt investigation of the same is established. Laboratory should initiate corrective actions for all the non-conformances identified. Effective and compliant management of nonconformities involves several steps. Each step should be documented.

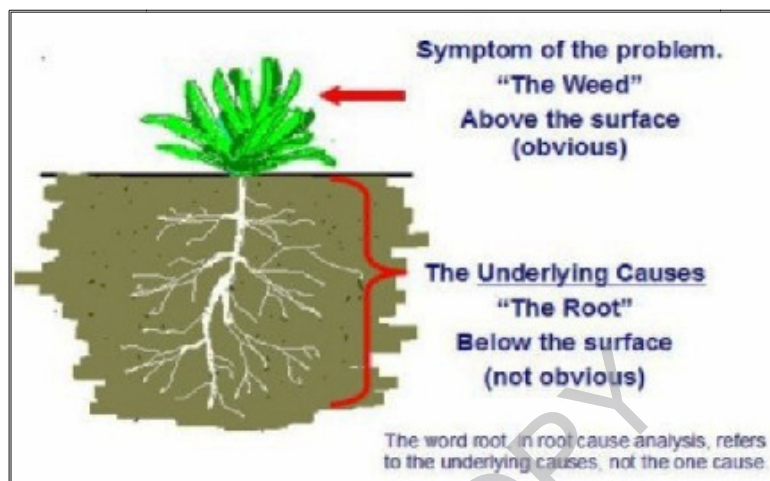
### Process steps for Corrective Action:

This is the reiteration and continuation of the above section on non-conformances (4.9).

1. **Identification of the nonconformity/occurrence/error:** Laboratory should define the nonconformity/occurrence/error including source of the information, brief description and supporting evidences for it. All the related information such as data, source documents, PT reports or audit reports which confirms the presence of problem should be included.
2. **Assessment:** The significance of the nonconformity should be critically evaluated. This helps in diagnosing the impact and magnitude of the problem related to the nonconformity. Appropriate staff should be involved to assess the medical significance of the nonconformity.
3. **Initiate immediate/remedial action if required:** The appointed staff should communicate appropriately about the nonconformity/occurrence to all those affected. If required, testing should be paused and reports should be withheld. In case the results are already released, reports should be recalled and the customers should be notified. If the results are yet to be released, each should be reviewed before release. Testing should be resumed only after signalled by the concerned authority.

#### 4. Root Cause Analysis (RCA):

Root Cause Analysis is a process for identifying the basic or causal factor(s) that underlies variations in performance, including the occurrence or possible occurrence of a nonconforming event.



*Figure 12: Root Cause*

It should be carried out by organizing a team consisting of laboratory staff familiar and related to the problem. RCA includes majorly three processes-

- Identify what exactly happened,
- Why it happened and
- Determine forward actions to prevent reoccurrence.

The root cause of the problem is identified by systematic and structured approach. Create a list of all the causes with relevant data to determine the primary cause of it. Consider the following and their role in the event/occurrence:

- Man
- Method
- Materials
- Machine
- Measurement/Maintenance/Mother nature

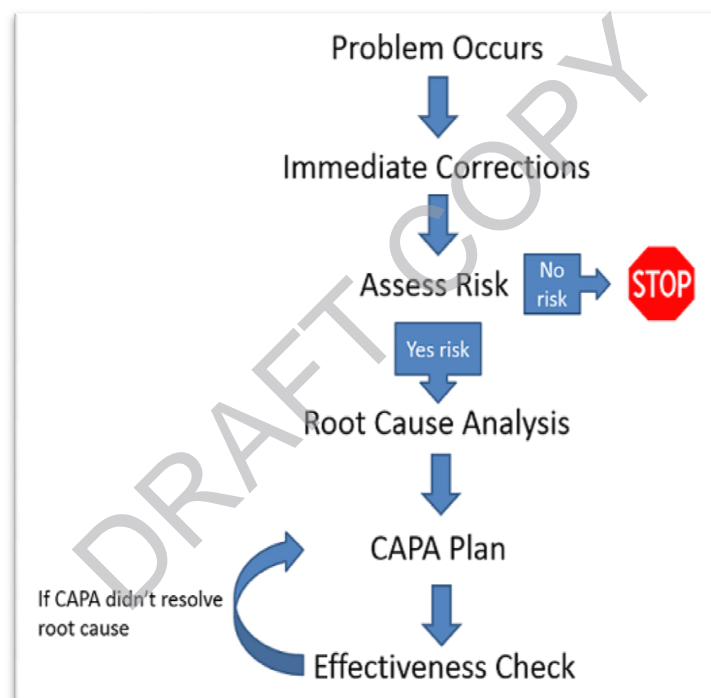
Root cause analysis tools like 5 Whys, Fishbone Analysis, etc. can be used. Any hidden causes should also be identified. It may be circumstances related to personnel, equipment, reagents, training, etc.

*For more details, refer to the training module on Quality Control Vol 1*

5. **Selection of corrective action:** After the identification of cause(s), the corrective action should be determined to resolve the problem. Laboratory should define the actions that

should be taken to eliminate the problem, person responsible and timelines for implementation.

6. **Implementation:** Implement the suggested corrective action considering whether similar problems exist in other areas of the laboratory. All the arrangements related to resources, finance, equipment, individual responsibilities and a schedule for implementation and completion should be specified.
7. **Communication:** Laboratory staff should be involved in the improvement process. Laboratory should have processes to communicate the quality issues, changes, outcomes and trends to personnel responsible as well as staff.
8. **Follow-up and verification:** A thorough follow up with monitoring, observation and verification of the completion of all tasks should be performed to avoid any recurrence of the same nonconformity. An assessment of the appropriateness and effectiveness of the corrective actions should be performed. The results of any nonconformity assessment should be communicated to management forming a part of periodic management review.



*Figure 13: Corrective Action Plan*

- ❖ It is imperative that the corrective action team/designated individual have **adequate process knowledge, medical expertise and authority to implement corrective action**.
- ❖ The **responsibility for monitoring for occurrence belongs to everyone** in the laboratory.
- ❖ Laboratory management should confirm the **availability of necessary resources** required for the implementation of corrective action.

## Documentation:

Laboratory should have a documented procedure for corrective action to be taken and its documentation whenever non-conformity is identified. All the nonconformities should be logged and documented properly. Laboratory should document each course of investigation, plan and action for record. The records should be maintained for the period as defined by the laboratory.

### 7.3 Preventive Action (4.11)

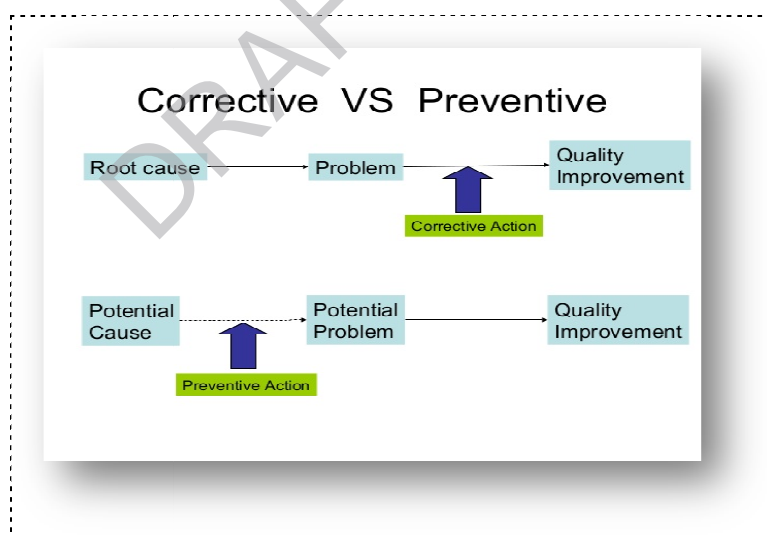
#### What is a Preventive Action?

Preventive action is the proactive action/s taken to eliminate the cause of a potential nonconformity or any other potentially undesirable situation or actions taken to improve a process to prevent potential future occurrences of non-conformity.

#### Difference between Corrective Action and Preventive Action:

Both preventive and corrective actions are steps taken to improve a process or to correct a problem. Corrective action is taken to rectify the cause(s) of nonconformities **to prevent recurrence** while preventive action is taken to **prevent occurrence**. Corrective action is an active process whereas preventive action is a proactive process.

**Corrective action prevents recurrence and preventive action prevents occurrence.**



*Figure 14: Difference between Corrective Action and Preventive Action*

The term potential implies possibility. The lab is required to understand all possible problems before it manifests.

Need for Preventive Action may be detected through

- External/internal audit findings

- Trends in process data
- Trends of root causes for nonconformities or complaints
- Quality reviews
- Quality risk analysis

These will be discussed in detail under 'Evaluation and audit' (4.14)

Preventive actions involve a planned and organized evaluation of processes and procedures to identify potential error points, so action can be taken to prevent the errors from ever occurring and aid quality improvement. It should be taken whenever an unacceptable trend is detected in any process of a laboratory. Preventive actions require planning and team participation.

The laboratory should establish and document a procedure (as indicated earlier, this can be included in the common QSP for 4.9-4.12) for:

- Reviewing laboratory data and information to determine where potential nonconformities exist
- Determining the root cause(s) of potential nonconformities
- Evaluating the need for preventive action to prevent the occurrence of nonconformities
- Determining and implementing preventive action needed. The preventive action taken should be appropriate to the effects of the potential problems.
- Recording the results of preventive action taken
- Reviewing the effectiveness of the preventive action taken.

*Note: Information regarding preventive actions should be subject to management review in support of maintaining and improving the effectiveness of the Quality Management System.*

## **7.4 Continual Improvement (4.12)**

The continual improvement of the laboratory processes is a dynamic set of activities to improve the effectiveness of quality management system. Continuous Quality Improvement (CQI) should be applied to all procedures and processes that are a part of the path of workflow in laboratory. Designing and implementing strategies to prevent or reduce errors or to detect and correct them before the reporting of the test result, constitutes quality improvement.

Effective continual improvement process warrants an understanding of all challenges as well as opportunities for improvement. The Quality Manager is the key person who can bring about this awareness usher in the improvement process. An effective Quality Management System provides the ideal tools for continual improvement in laboratory

#### 7.4.1. Quality Indicators (ISO: 15189 4.14.7):

*Note: Technically, the following concepts are part of ISO: 15189 4.12 Continual Improvement as well as ISO: 15189 4.14; Evaluation and Audits. The reader is required to understand it also as part of ISO15189:4.14.*

A Key Performance Indicator is a measurable value that demonstrates, at a glance, how well any operation is performing in defined parameters. In a laboratory QMS, quality indicators assume the role of KPIs. Thus a Quality Indicator (QI) is a measurement followed by analysis to address how well the laboratory is meeting the user needs.

Laboratories should set quality objectives and goals to evaluate activities and obtain necessary data to measure the performance of that objective.

The process of setting quality objectives and indicators is illustrated with an example from the analytical phase of the Biochemistry dept. of a lab.

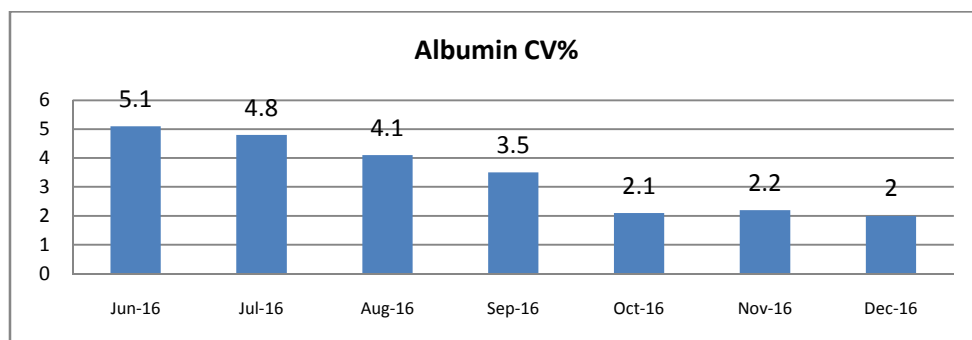
Assume that the following was the %CVs (Measure of imprecision) of a lab for a certain month and the acceptable CV%

Monthly CV data of a laboratory for the month of June 2016		
Analyte	Observed CV%	Acceptable CV%
Albumin	5.1	1.6
Glucose	4.8	2.3
Urea	5.5	6.1
Creatinine	3.1	3.0

Column 1 shows the name of the analyte, and columns 2 and 3 show the observed and acceptable CV% (as per BV desirable database) for the analyte, respectively. What are the Quality Objectives and Quality Indicators that may be set?

The **Objective** here, would be to bring down the CV% to acceptable levels. **Action** required would involve stabilising the analytical system through proper preventive maintenance of the equipment, monitoring reagent storage conditions, monitoring the lab environment, storage of QC and calibrators, reviewing calibration frequencies.

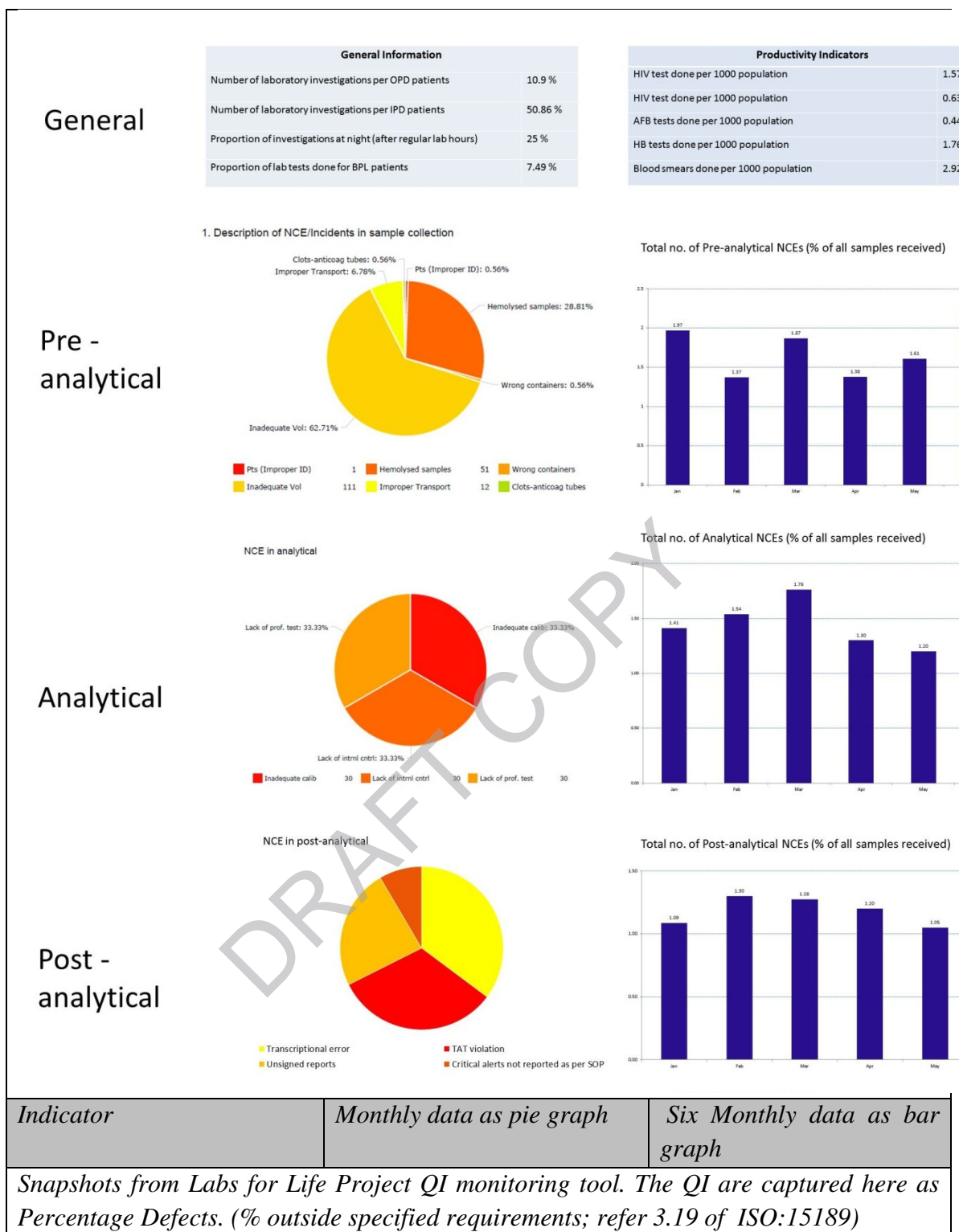
The **Indicators** would be tracking the CV % of each analyte. To continue the illustration, CV% of S. Albumin has been tracked over a period of 6 months and shows improvement and meeting the quality objective of achieving acceptable levels of precision.



Once the quality objective has been achieved, as in the above case, the lab may move on to other objectives, but it must continue to track the CVs as Quality Indicators, for the purpose of continual improvement.

**Dashboard:** In information technology, a dashboard is a user interface that, somewhat resembling an automobile's dashboard, organizes and presents information in a way that is easy to read. In a lab, for quick evaluation of quality indicators, a Dashboard can be used. All the Quality Indicators and other performance indicators can be displayed as a dashboard for quick reference. An example of such a dashboard is given below. A few productivity indicators and Quality Indicators in the pre-analytical, analytical and post analytical areas of operation are plotted. A monthly pie chart (QI wise) and a continuous bar chart (area of operation-wise) are plotted by this software. In saying this, it has to be reiterated that, identification of the non-conformities is the most crucial step in the process of the improvement process. The labs are well advised to enable a system towards these at each point of operation.





## 7.4.2. Management of nonconformities:

**The Deming Plan-Do-Check-Act (PDCA) Cycle is the best way to confirm continual improvement. It is a four step looping process:**

**Plan** — identify the problems and potential sources of any system weakness or error by implementing a regular structured review of all operational procedures by laboratory. Develop a plan from the collected information.

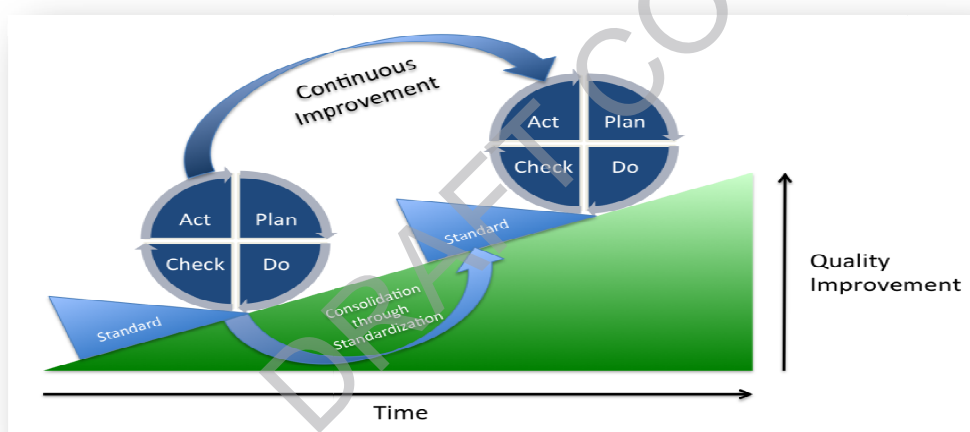
**Do**— implement the plan and put it into action.

**Check** — this refers to the monitoring process. Also, assess the effectiveness of the action using focused review and audit.

**Act** — Implement the action plan and implement changes to the quality system in accordance with the review and audit results. Take any corrective action that is required, and then re-check to ensure its effectiveness.

*Note: The quality system should be reviewed for redundancies and inherent weaknesses especially in areas that have frequent non-conformances or complaints, closer scrutiny should be applied.*

As this diagram indicates, continual improvement is a process of incremental improvement of planning-doing-checking-acting with the standard as the reference.



*Figure 15: Deming Cycle*

*For Control of records (4.13), please refer to the Documentation Module*

## Chapter 8 - Evaluation and Audits (4.14)

**Learning Objectives:** At the end of this chapter, the learners should be able to understand the

- Evaluation criteria for Quality Systems
- Definition, process and importance of audits
- Definition, process and importance risk assessment
- Reviews by external organizations

### 8.1 General

Nonconformities to the ISO standards may arise from deviations from requirements which can be pointed out by:

- Routine process audits, to be identify NCs in day to day to day work. Internal policies and procedures of an organization of recording non-conforming events (discussed earlier) must be in place for this
- Audits: Internal and external audits
- Risk Assessments
- Quality Indicators
- Staff suggestions
- Feedback from users

### 8.2 Audits

Audits are means of collecting factual, unbiased information about how well an organization's quality system is functioning. Assessment is an important tool to demonstrate that the laboratory is meeting regulatory, accreditation, customer and organizational requirements. The ISO definition for audit is a "systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which required criteria are fulfilled."

The evaluation and internal audit processes are needed to:

- Demonstrate that pre-examination, examination and post-examination processes meets the needs and requirements of the users;
- Ensure conformity to the quality management system;
- Continually improve effectiveness of the quality management system.

Actions required may include:

- Periodic review of collection processes. E.g. If the laboratory is using non-standard techniques like reusable tubes, they may be amended.
- Periodic review of analytical processes. If an analytical process fails to meet standards, this may be reviewed, and alternate methods looked into.

- Periodic review of post-analytical processes. Problems of transcription errors, or meeting TAT, electronic options viz. LIS may be considered

*Note: Accepted standards, whether national, international, local or standards from accrediting organizations form the guide to be followed by the laboratory.*

### **Different Types of Audits:**

- First party audit** : The laboratory auditing itself on a regular basis for continual improvement
- Second Party Audit**: It is an external audit performed by a customer or a contracted organization (e.g. Insurance agencies) on behalf of a customer to ensure meeting of requirements specified in the contract.
- Third Party Audit**: It is an external audit performed by an audit organization independent of customer-client relationship or certification bodies or regulatory agencies like ISO (International Organization for Standardization), NABL (National Accreditation Board for Testing and Calibrating Laboratories), CAP (College of American Pathologists), etc. for certification, accreditation or regulatory purposes.
- Internal Audits**: Internal quality audits are audits carried-out by the laboratory's personnel. It may be coordinated by the Quality Manager and is a strict requirement of the ISO
- External Audits**: An assessment, by a body commercially and contractually independent of the organization, i.e. suppliers, regulators and customers

### **Internal Audit: (ISO 15189: 4.14.5)**

Internal audits examine the elements of the quality management system in the laboratory to evaluate how well these elements comply with quality system requirements and assure continual improvement in the quality system. They are also required by ISO 15189.

### **Purpose:**

The laboratory should conduct internal audits to determine whether all activities the quality management system, including pre-examination, examination and post-examination:

- Conform to the requirements of the ISO Standard
- Conform to the requirements established by the laboratory
- Are implemented, effective and maintained.

*Note: The purpose of the internal audits is not to search for the guilty, or to find fault with individuals' performance. The system is being audited - not the individuals.*

### **Requirements:**

Internal audits should be conducted as per criteria, scope, intervals and methods defined and documented in quality management system.

## 1. Scope

- i. If the lab has three depts., audits must be undertaken in all these depts.
- ii. Both management and technical areas must be audited
- iii. Pre-analytical, analytical and post- analytical areas should be audited

**2. Interval** – As per NABL recommendations, IA should be done once a year, before the MRM. But may be done more frequently if warranted.

**3. Checklist** - Any validated checklist may be used.

Checklists are generally made in the following manner –

- Areas needing standardization are identified
- Standards are defined
- Checkpoints are defined



*Figure 16: Making of a Checklist*

Checklist 1 & 2 of NABL 217 may be used. (This is a downloadable NABL document and for use in the laboratory, the NABL footer may please be removed). NQAS checklist of NHM, LQMS checklist of IDSP may also be used. It should be kept in mind that all elements of ISO15189 are checked. Any checklist used should be validated by the auditor before use. For NABL accreditation, checklist 217 is recommended.

Checklist NABL 217 is statements of the standard and the checkpoints have to be understood by the auditor. Alternatively the auditor may refer to the NQAS/SLIPTA/WHO Checklists for this purpose.

## 4. Method

- Internal audits should be planned in advance and the audit programme or schedule should be communicated to all the personnel in all depts. /areas in the laboratory. The detailed schedule with date, time, and area to be audited should be communicated well in advance.
- The results of previous audits and closure of NCs may be made available to all stakeholders
- It can be performed by an individual or a group of people trained to assess the performance of managerial and technical processes of quality management system as per ISO 15189 Standard.
- The auditors should be independent of the activity they are auditing to ensure objectivity and impartiality. This means the laboratory personnel of one dept./area should not audit their own activities.

## 5. Process:

The auditing procedure consists of the following steps:

### Audit preparation

The Quality Manager is responsible for the coordination of the audit and will choose the auditor(s), dates and times of audit, and the checklist to be used and will also prepare the lab towards the audit

### The Auditor

- For purpose of NABL accreditation, the internal auditor should have done training on Internal Audit by a NABET certified agency
- Should be familiar with the applicable local regulations and guidelines
- Should be familiar with the checklist
- Should read through the previous audit reports covering the same area

### Auditing

The auditor should audit as follows:

- Starting with an opening meeting.
- Using standard auditing techniques and objective information concerning the subject being audited should be collected.
- Documentary evidence of conformity or nonconformity should be collected. (NAF4 of 217 may be used to document NCs)
- Points where current procedures could be improved should be noted.

### Writing the audit report

After the audit, the auditor should prepare an audit report which– classifies the findings of the audit as follows:

- Acceptable: satisfies the requirements of ISO 15189 and the laboratory's own standards, procedures, manual, etc.
- Major non-conformances :those which affect patient care directly e.g. any violation in 5.5, 5.6
- Minor non-conformances : those that may not satisfy the requirements of ISO 15189 fully, but may not affect the patients directly e.g. a missing sub-clause in an SOP
- Observation: an area of weakness that could be improved or a comment on something done well e.g. an additional job aid that might help

The report should be signed off by all the participants (the auditor, auditees and observers) stating location and date of the audit.

### Following-up

- The laboratory should undertake appropriate corrective or preventive actions, which should be documented and carried out within an agreed upon time. Follow-up and

monitoring of the implementation and effectiveness of the corrective action, and if required, preventive action, should be done and documented (Figure 17).

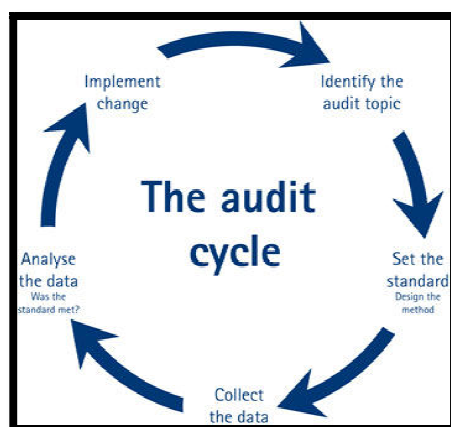


Figure 17: Audit Cycle

#### 6. Documentation:

- The laboratory should retain record of audits including audit programme, records of meetings, audit report, corrective and preventive action taken, follow-up report and verification.
- The results of internal audits should be submitted to laboratory management for review.

*(Annexure I: Sample format of an audit record)*

#### 8.3 RISK MANAGEMENT (4.14.6)

Risk is a combination of probability of occurrence of harm and the severity of this damage.

Risk analysis is the systematic use of available information to identify hazards and to estimate risk.

Risk assessment is identifying potential failure modes, determining severity of consequences, identifying existing controls, determining probabilities of occurrence and detection, and evaluating risks to identify essential control points.

Risk management is the identification, analysis and economic control of those risks which can threaten the assets or earnings of an enterprise.

CLSI EP 23 refers to a process of depicting risk factors on a risk assessment matrix to evolve strategies of intervention.

Risk has three components- the **probability of occurrence of harm, the consequences of that harm and detection rate**. Based on the identified risk, a RPN (Risk Prioritization Number) is calculated. Appropriate measures are implemented to mitigate each risk factor. The laboratory has established risk management plan for the above mentioned phases of testing.

$$\text{Risk prioritization score (RPN)} = \text{Severity of harm} \times \text{Likelihood of occurrence} \times \text{Detection rate}$$

#### Areas of risk in a medical laboratory:



Figure 18: Areas of Risk

In ISO: 15189, the risk assessment pertains to the risk of errors in patient reporting on account of faulty work processes and ensuing failure on examination results. A risk is a potential error waiting to happen putting the patient result and safety in danger.

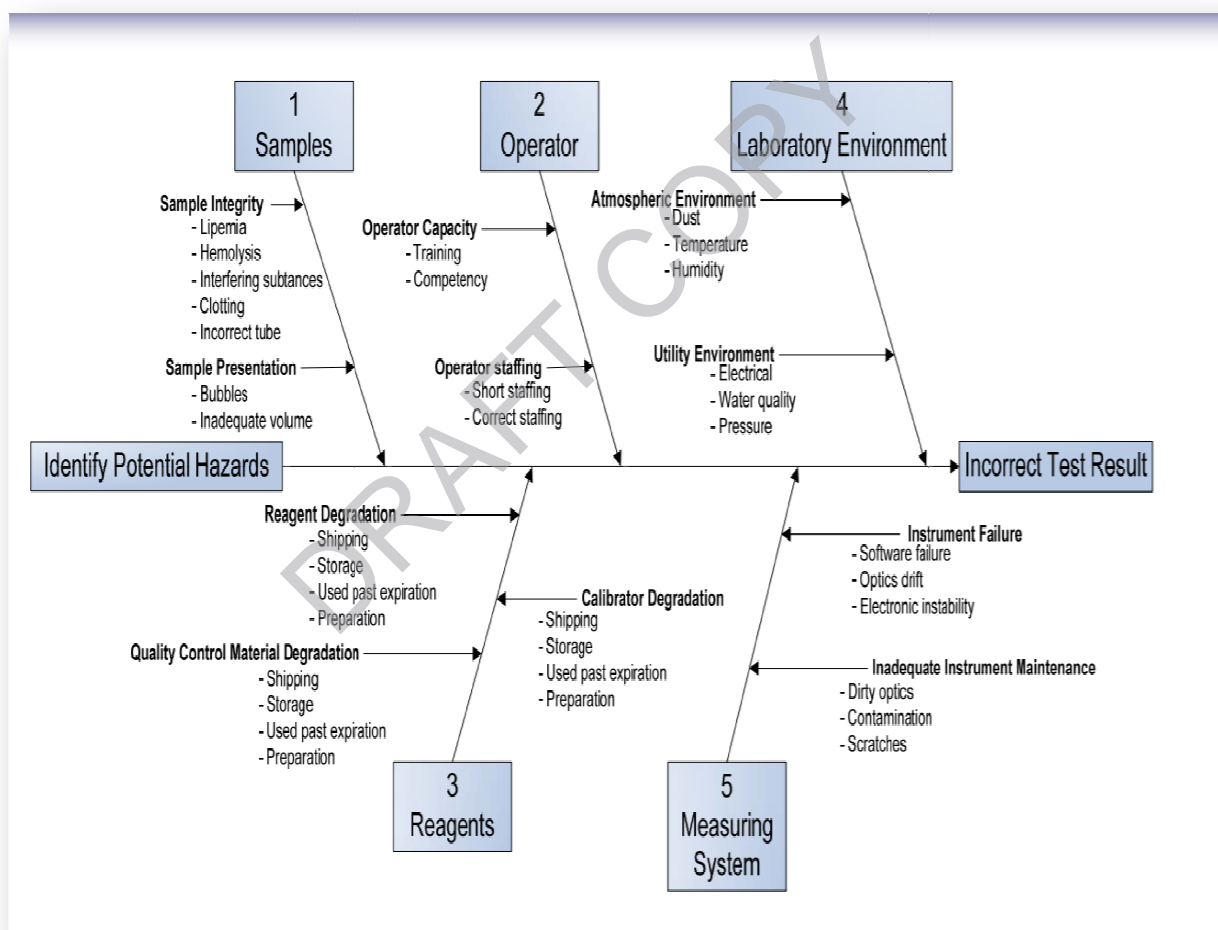
Risk management includes steps, planning of risk, identifying the risk and its impact, developing and establishing risk handling plans and monitoring for risk control. It helps in preventing errors and clinical hazards.

This evaluation should include identifying the potential for error in five main areas:

- **Specimen:** The specimen may be at risk for error in the pre-analytic phase. Evaluate critical steps in specimen collection, labelling, storage requirements, stability and transport to the testing lab, processing, acceptability, and rejection criteria.
- **Environment:** The environmental conditions in the laboratory can affect the test system's performance, for example, temperature, airflow/ventilation, light intensity, noise and vibration, humidity, altitude, dust, water quality, electrical failure/power supply variance or surge, and adequate space.
- **Reagent:** The reagents, quality control materials, calibrators, and similar materials required for test processing are susceptible to failure with shipping/receiving, storage conditions, expiration date (unopened/opened state), and preparation.



- **Test System:** This risk assessment will primarily cover the analytic and post analytic phase of testing and must consider function checks and maintenance as required by the manufacturer. This may vary with the laboratory's test volume and intended use of the test results (i.e., screening or diagnostic). Factors in this category are quite variable: — inadequate sampling, clot detection capabilities, capability for detection of interfering substances (e.g., hemolysis, lipemia, icterus, turbidity) calibration-associated issues — optical, pipettes, sample probes, barcode readers —built-in procedural and electronic controls, liquid quality controls, temperature monitors and controllers
- **Testing Personnel:** This potential risk relates to training and competency assessment. The impact of inadequate training, ongoing competency, appropriate education and experience qualifications of staff, and adequate staffing resources can be significant in test systems that are highly complex.



*Figure 19: Identifying Potential Hazards for an Incorrect Test Result (ISO 15189:4.14.6)*

A laboratory should establish, document and maintain throughout the life-cycle, an ongoing process, provisions for identifying hazards associated, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the controls.

*(Annexure J2: Example of a Risk assessment and management record)*

An example: Assume that the CV% of a parameter is unacceptably high. It immediately points to a risk of imprecision. All factors described above must be checked and root cause determined. Additionally, the laboratory is required to understand other aspects of quality such as the bias through peer group data to assess the inaccuracies and from there the total error. The laboratory should then compare it with available quality specifications and decide whether the method is acceptable and fit for purpose. If not, the method should be changed.

*For more details, refer to Quality Control module, Vol. 1*

## **8.4 QUALITY INDICATORS(4.14.7)**

*This has already been discussed in Chapter 7, however some more details are provided below.*

Quality indicators are established measures used to determine how well an organization meets needs and operational and performance expectations.

All laboratories should implement a process to monitor and evaluate laboratory performance by using a set of indicators which cover at least one element or activity from pre-examination, examination, and post-examination phases that needs improvement.

### **Points to consider while developing and setting quality indicators:**

- Good Quality Indicators are measurable, achievable, interpretable, actionable, balanced, engaging and timed.
- While deciding the quality indicators, the concept of path of workflow in the laboratory should be considered. A minimum of 2 per area; pre-analytical, analytical and post analytical may be considered.
- Too many quality indicators at a time become hard to be tracked.
- Quality indicators that will be most meaningful for the laboratory must be selected.
- The objectives, methodology and duration of measurement should be established.
- A quality indicator should be monitored (e.g. monthly, quarterly or six monthly) and as long as it is useful.
- Improvement in a quality indicator is achieved by planning and involving all stakeholders
- After it results in steady and acceptable performance, it should be replaced by a new one.

Some examples of quality indicators are listed below:

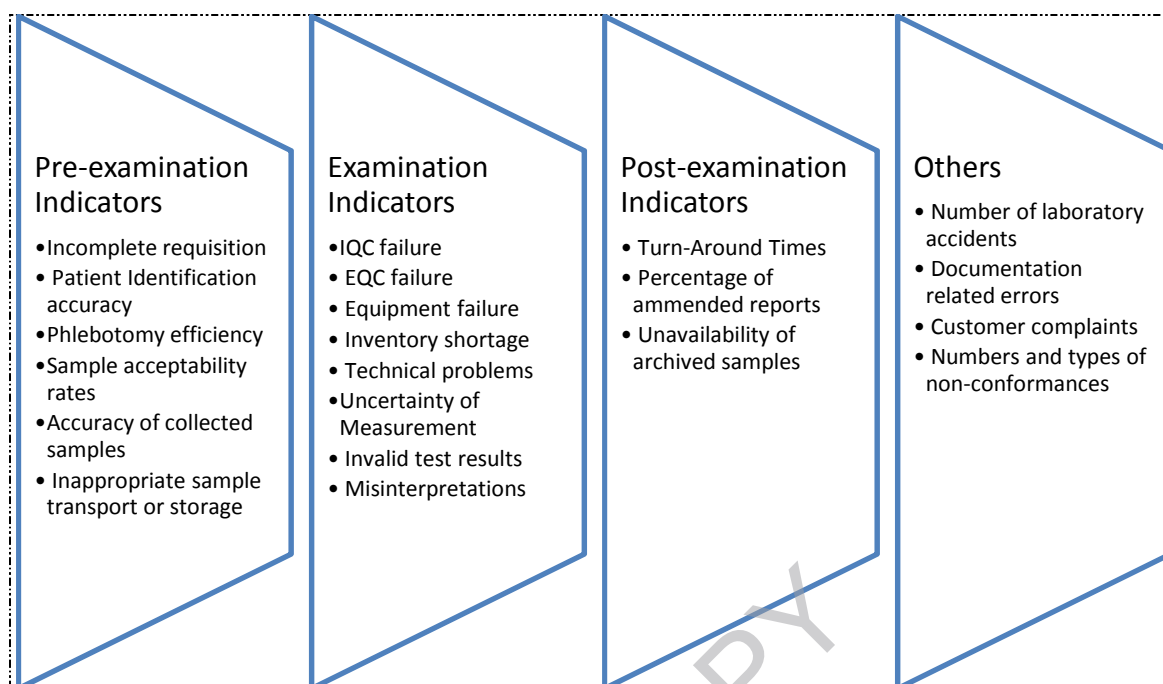


Figure 20: Some Quality Indicators

## 8.5 Reviews By External Organizations: (4.14.8)

The reviews about the performance of the laboratory can be obtained through accreditation organizations which includes accreditation assessments, regulatory agencies' inspections, and health and safety inspections. This process can also be termed as external audit. The assessors will verify that laboratory policies, processes and procedures are documented and comply with designated standards. Different standards can be used for the assessment processes. Examples of audits using ISO 15189 standards are NABL, NQAS, LQMS (WHO). Other kinds of audits include MCI, PCBs, etc.

After the review, the recommendations of the assessors are presented as nonconformities or potential nonconformities to the laboratory management and staff, which are then followed by a thorough written report. The laboratory should review the recommendations of the assessors, take appropriate immediate action(s) and as appropriate corrective action(s) or preventive action including timelines and who is responsible to ensure continuing compliance with the International Standards.

All the actions taken including reviews, corrective action and preventive action taken should be recorded and stored.

## Chapter 9 - Management Review (4.15)

**Learning Objectives:** At the end of this chapter, the learners should be able to understand the

- Various aspects of management review
- Process and importance of management review

Management review is evaluation of the overall performance of an organization's quality management system and identification of improvement opportunities. These reviews are carried out by the organization's top managers and are done on a regular basis.

Management review is a periodic meeting of management at which it reviews the status and effectiveness of the quality management system of the laboratory. It acts as a mode of evaluation and analysis of current practices for the purpose of quality improvement.

Management review is a valuable component of the quality management systems including medical laboratory QMS in accordance with ISO 15189. It is the responsibility of the Quality Manager to plan, schedule and coordinate the MRM. An MRM is generally conducted after the Internal Audit. This will enable the management to understand the needs of the laboratory and address them adequately. The frequency of management reviews should not be more than 12 months. However, when a QMS is being established, shorter intervals should be fixed. Quarterly reviews are recommended to keep both technical and managerial functionaries in contact and engaged in the quality improvement process.

The report of the management review meeting (MRM) is mandatory for application for accreditation. The three components of the MRM are –

- Review inputs
- Review activities
- Review outputs

### Review Inputs

They imply the data/information submitted by the technical team to the management team for deliberations.

The input to management review should include information from the results of evaluations of at least the following:

- The periodic review of requests, and suitability of procedures and sample requirements.
- Assessment of user feedback

- Staff suggestions
- Internal audits
- Risk management
- Use of quality indicators
- Reviews by external organizations
- Trends in IQC programs
- Results of participation in inter-laboratory comparison programmes, PT/EQA
- Monitoring and resolution of complaints
- Performance of suppliers and inventory management
- Identification and control of nonconformities
- Results of continual improvement including current status of corrective actions and preventive actions
- Follow-up actions from previous management reviews
- Changes in the volume and scope of work, personnel, and premises that could affect the quality management system
- Recommendations for improvement, including technical requirements.

The lab may however choose to include any challenges like staff availability/attrition, training and CME opportunities and other specific challenges.

### **Review Activities:**

At the review, the management is required to analyse the input information and determine the causes of nonconformities, trends and patterns that indicate process problems. The management should also look at opportunities for improvement and the need for changes to the quality management system. The quality policy and quality objectives may be reviewed and amended. New objectives may be set and new indicators defined to enhance the laboratory's contribution to patient care.

### **Review Outputs:**

The decisions at the MRM should be documented and minutes circulated and explained to all lab members. The responsible persons should be oriented towards any new objectives and indicators chosen at the MRM.

Reports of the management review should be retained for the time interval as stated in guidelines. (*Annexure L:Format of a Management Review meeting record, Sample*)

## REFERENCES:

1. ISO 15189:2012: International Standard: Medical Laboratories- Particular requirements for quality and competence. Third edition.
2. Laboratory Quality Management System: Version 1.1, 2011, WHO.
3. NABL 112: Specific Criteria for Accreditation of Medical Laboratories.
4. NABL 161: Guide for Internal Audit and Management Review for Laboratories.
5. International vocabulary of metrology — basic and general concepts and associated terms (VIM): JCGM 200:2008.
6. CLSI GP26-A4QMS: A Model for Laboratory Services
7. CLSI EP23-A, Laboratory Quality Control Based on Risk Management; Approved Guidelines

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## Glossary

<b>Accreditation</b>	: Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Reference: ISO 15189
<b>Accuracy</b>	: The closeness of a measurement to its true value.
<b>Audit</b>	: A documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the quality system are suitable and have been developed, documented, and effectively implemented in accordance with specified requirements
<b>Compliance</b>	: An affirmative indication or judgement that the supplier of a product or service has met the requirements of the relevant specifications, contract or regulation; also the state of meeting the requirements. Meets both the text and the spirit of a requirement.
<b>Incidence</b>	: An individual occurrence of brief duration or secondary importance
<b>ISO Standards</b>	: A set of international standards providing guidance for quality in the manufacturing and service industries; developed by the International Organization for Standardization (ISO) to help companies effectively documents the quality system elements to be implemented to maintain an efficient quality system. The standards, initially published in 1947, are not specific to any particular industry, product or service; they are broadly applicable to many kinds of organizations.
<b>NABL</b>	: National Accreditation Board for Testing and Calibration Laboratories (NABL) is an autonomous body under the aegis of Department of Science & Technology, Government of India, and is registered under the Societies Act.
<b>Non Conformance</b>	: Non-fulfilment of a requirement
<b>Indicators</b>	: Established measures used to determine how well an organization is meeting its customers' needs as well as other operational and financial performance expectations
<b>Organogram/Organization Chart</b>	: Defines the working structure for the organization; organizes jobs along lines of authority; defines reporting

	structure and span of control; defines authority to make decisions and accountability for results; works together with job descriptions to define the working structure of the organization.
<b>Process control</b>	: Concerns monitoring all operations of the laboratory.
<b>QMS</b>	: A quality management system (QMS) is a collection of business processes focused on achieving quality policy and quality objectives to meet customer. It is expressed as the organizational structure, policies, procedures, processes and resources needed to implement quality management. Early systems emphasized predictable outcomes of an industrial product production line, using simple statistics and random sampling
<b>Quality Assurance</b>	: A planned and systematic set of quality activities focused on providing confidence that quality requirements will be fulfilled.
<b>Quality Control</b>	: A set of activities or techniques whose purpose is to ensure that all quality requirements are being met. Simply put, it is examining “control” materials of known substances along with patient samples to monitor the accuracy and precision of the complete examination process.
<b>Quality Policy</b>	: Overall intentions and direction of an organization related to quality as formally expressed by top management. Reference: ISO 9000:2005.
<b>Risk Management</b>	: The identification, analysis and economic control of those risks which can threaten the assets or earnings of an enterprise.
<b>Sensitivity</b>	: Sensitivity is the lowest concentration of an analyte that can be measured. This is also LoD/LoQ
<b>Specificity</b>	: Artefactual increase or decrease of quantity of analyte due to the presence of any interfering substance(s).
<b>TAT</b>	: Length of time that a sample’s final result may be issued to the ordering physician.
<b>Validation</b>	: Confirmation, through provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.



## List of Abbreviations

<b>AMC</b>	:	Annual Maintenance Contract
<b>BMW</b>	:	Bio-Medical Waste
<b>CA</b>	:	Corrective Action
<b>CAP</b>	:	College of American Pathologist
<b>CAPA</b>	:	Correction and Preventive Action
<b>CLIA</b>	:	Clinical Laboratory Improvement Amendments
<b>CLSI</b>	:	Clinical & Laboratory Standards Institute
<b>CMC</b>	:	Comprehensive Maintenance Contract
<b>CME</b>	:	Continuing Medical Education
<b>CMO</b>	:	Chief Medical Officer
<b>CQI</b>	:	Continuous Quality Improvement
<b>CV</b>	:	Coefficient of Variation
<b>EQA</b>	:	External Quality Assessment
<b>HICC</b>	:	Hospital Infection Control Committee
<b>HOD</b>	:	Head of Department
<b>HR</b>	:	Human Resource
<b>IDSP</b>	:	Integrated Disease Surveillance Programme
<b>IPHS</b>	:	Indian Public Health Standards
<b>ISO</b>	:	International Organization for Standardization
<b>IT</b>	:	Information Technology
<b>LIS</b>	:	Laboratory Information System
<b>LQMS</b>	:	Laboratory Quality Management System
<b>MCI</b>	:	Medical Council of India
<b>MoU</b>	:	Memorandum of Understanding
<b>MRM</b>	:	Management Review Meeting
<b>NABET</b>	:	National Accreditation Board for Education and Training
<b>NABL</b>	:	National Accreditation Board for Testing and Calibration Laboratories
<b>NC</b>	:	Non conformance
<b>NCE</b>	:	Non-Conforming Event
<b>NHM</b>	:	National Health Mission
<b>NQAS</b>	:	National Quality Assurance Scheme
<b>NVBDCP</b>	:	National Vector Borne Disease Control Program
<b>PCB</b>	:	Pollution Control Board
<b>PDCA</b>	:	Plan Do Check Act
<b>PMO</b>	:	Primary Medical Officer
<b>PT</b>	:	Proficiency Testing

<b>QC</b>	:	Quality Control
<b>QM</b>	:	Quality Manager
<b>QMS</b>	:	Quality Management System
<b>QSP</b>	:	Quality System Protocols
<b>RCA</b>	:	Root Cause Analysis
<b>RPN</b>	:	Risk Prioritization Number
<b>SACS</b>	:	State AIDS Control Society
<b>SLIPTA</b>	:	Strengthening Laboratory Management Towards Accreditation
<b>SOP</b>	:	Standard Operating Procedure
<b>SQAC</b>	:	State Quality Assurance Committee
<b>TAT</b>	:	Turn Around Time
<b>WHO</b>	:	World Health Organization

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## Annexure

### Annexure A: Confidentiality undertaking by the employee (to be submitted at the time of induction): Sample

I understand and acknowledge that:
1. I shall respect and maintain the confidentiality of all discussions, deliberations, patient care records and any other information generated in connection with individual patient care, risk management and/or peer review activities.
2. It is my legal and ethical responsibility to protect the privacy, confidentiality and security of all information relating to the laboratory, including business, employment and medical information relating to our patients, members, employees and health care providers.
3. I shall only access or disseminate patient care information in the performance of my assigned duties and where required by or permitted by law, and in a manner which is consistent with officially adopted policies of the institute/hospital, or where no officially adopted policy exists, only with the express approval of my supervisor or designee. I shall make no voluntary disclosure of any discussion, deliberations, patient care records or any other patient care, peer review or risk management information, except to persons authorized to receive it in the conduct of lab affairs.
7. I understand that any and all references to HIV testing, such as any clinical test or laboratory test used to identify HIV, a component of HIV, or antibodies or antigens to HIV, are specifically protected under law and unauthorized release of confidential information may make me subject to legal and/or disciplinary action.
8. I understand that the law specially protects psychiatric and drug abuse records, and that unauthorized release of such information may make me subject to legal and/or disciplinary action.
9. My obligation to safeguard patient confidentiality continues after my termination of employment or affiliation with the laboratory.
I hereby acknowledge that I have read and understand the foregoing information and that my signature below signifies my agreement to comply with the above terms. In the event of a breach or threatened breach of the Confidentiality Agreement, I acknowledge that institute may, as applicable and as it deems appropriate, pursue disciplinary action as described in the bylaws.
I further understand that I may also be subject to civil or criminal legal penalties if I violate these security policies.
Dated: _____
Name & Signature: _____

## Annexure B: Consent Form for FNAC: Sample

### FNA Consent Form

Patient Name \_\_\_\_\_

Patient DOB: \_\_\_\_/\_\_\_\_/\_\_\_\_

The procedure of Fine Needle Aspiration (FNA) will consist of the following:

A needle will be inserted into the neck mass from 1 to 4 different angles; the samples will then be sent out for cytopathology evaluation.

#### **Complications may include:**

Pain at the injection sites, infection, and air trapped under the skin, mild bleeding

I confirm that I do not have any bleeding disorders, and have abstained from blood thinners or aspirin therapy for 5 days prior to the procedure.

I have read and consent to have a Fine Needle Aspiration performed by Dr. XYZ

Patient's signature \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

#### Post FNA Instructions

1. Do not take aspirin for 2 days following the procedure.
2. Take painkillers every 6 hours as needed for pain, unless you are allergic to it.
3. If you experience sudden neck swelling, or shortness of breath, go to the nearest emergency medical service.

## Annexure C: Job description: Sample

**Job Title:** Laboratory Technical Manager

**Job Summary**

A Laboratory Technical Manager is responsible for managing a medical laboratory, including supervision of laboratory staff.

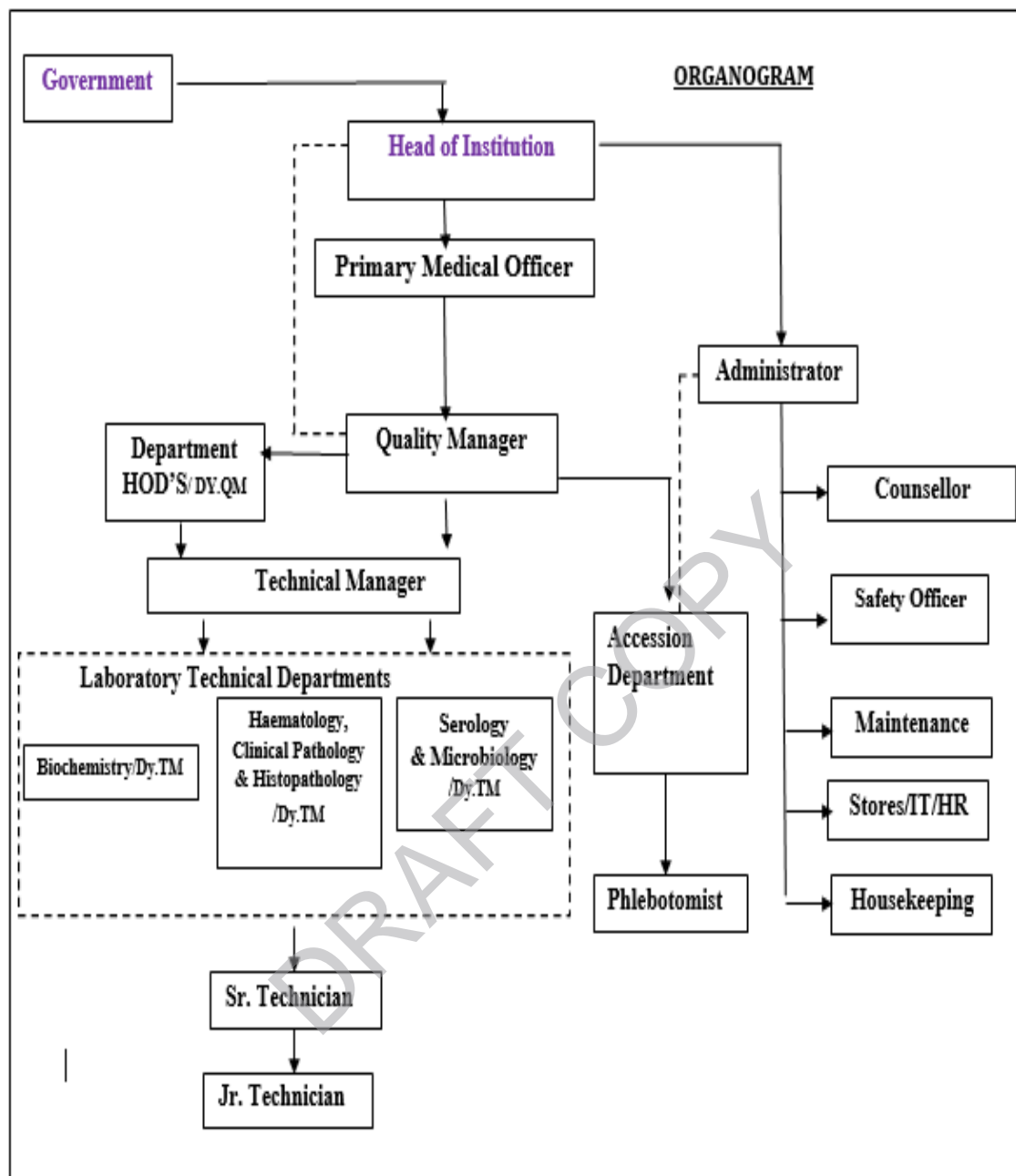
### **Nature of Work**

This position reports to a Director of the laboratory. This position receives assignments in terms of broad goals and is given considerable latitude for decision-making and establishing priorities in managing the laboratory. The Laboratory technical manager is responsible for supervising the various tests, results, software systems, quality control, and pricing for the lab, as well as supervising staff, primarily Medical Technologists.

### **Duties**

- To supervise and train staff in the performance of laboratory functions – both administrative and technical operating procedures. To evaluate staff proficiency and performance.
- To establish and implement written operating procedures and protocols for tests performed in the laboratory
- To establish and maintain a routine documented schedule of quality control and quality assurance, including external quality control.
- To develop and direct the statistical and record keeping software functions of the laboratory.
- To perform laboratory testing – haematology, immunohematology, bacteriology, mycology, urinalysis, immunology, chemistry, endocrinology, serology, and parasitology. To obtain and process specimens; perform tests; interpret and report results.
- To review test results, and follow-up on abnormal and critical values.
- To evaluate and establish costs/price for individual in-house tests with supervisor and independently negotiate price for off campus testing.
- To stay abreast of new tests, new procedures, and new technology in the medical technology field. To initiate discussion with medical and administrative personnel regarding implementation of new methodology, tests, and procedures as appropriate.
- To manage laboratory inventory, establish preventative maintenance schedule for equipment; oversee computerized records system.

## Annexure D: Organogram of a Public health Laboratory: Sample



## Annexure E1: Format for procedure for selection and evaluation of Referral laboratory: Sample

### 1. General Policy

It the policy of XYZ lab that any work that needs to be referred, in-house or to external laboratories, for whatever reason, are in compliance with this Quality Management System and requirements ISO/IEC 15189 International Standards and other regulatory agency requirements.

Referral laboratories are evaluated, selected and monitored by the management of XYZ lab. All method and instrument validations and comparisons are performed before work is placed with a referral laboratory or with a backup instrument.

### 2. Purpose

The purpose is to ensure that the use of referral laboratories is done in a standard way that does not compromise the Quality of XYZ service to its clients.

### 3. Scope

This procedure covers the entire test schedule of XYZ and refers to any occasion that may require the use of a backup system or referral of test work.

### 4. Responsibilities

#### *Quality Manager*

- Evaluation and monitoring of referral laboratories.
- Method and instrument validation and comparison of referral laboratories instruments and XYZ instruments.
- Performance comparison between primary and back-up instruments at XYZ.

#### *Lab Manager*

- Selection of the referral laboratories to use when the need arises.
- Approval of the use of referral laboratories as required.
- Identify all tests that require the use of referral laboratories.

#### *All staff*

- Ensure that they report all malfunctioning equipment to the Lab Manager by filling out a corrective action and problem report form.

#### *Referral Laboratories*

- Ensure that they fulfill XYZ conditions of service and requirements for referred work.



## 5. Procedures

### *Evaluation of Referral Laboratories*

All referral laboratories shall be evaluated before they can be short listed for selection. In the first phase of the evaluation process , evaluation form document number XYZ/001FR026 shall be used in the collection of information from potential referral laboratories. The second phase of the evaluation process shall involve method and instrument performance comparison between the referral lab and XYZ

### *Selection*

Once a method and instrument performance comparison is accepted, then cost factor evaluated and this is the responsibility of the Laboratory Manager. Reasons for selections shall be fully documented.

### *Monitoring*

Constant monitoring of the referring lab for continued compliance to requirements. This shall include bi-annual instrument comparison studies and annual initial evaluation process, EQA reports analysis, IQC reports analysis and Instrument performance checks.

### *Instrument Comparison*

Instrument comparison studies should be done biannually to ensure results from referral laboratory instruments and XYZ instruments agree. This should follow the procedures laid down in the SOP on Method and Instrument Validation. The same should be done for XYZ back-up systems. All maintenance checks should be performed to the back up system.

### *Using Back up Measures for Testing*

- Fill in the CAPA form when the non-conformity has been identified.
- Send CAPA form to the Laboratory Manager for assessment of the problem. Lab Manager approves the use of back up instrument or referral laboratory.
- Notify appropriate personnel, e.g. at referral lab that you will be sending samples, Lab staff to prepare the backup instruments.
- Send samples for testing ensuring that specimen integrity is maintained through the proper transport procedures.
- Evaluate results all result reports obtained from back up instruments or referral labs to ensure they conform to requirements.
- When corrective actions have been implemented and evaluated to have been effective, the original testing system can then be put back in place for normal operations to resume.

## 6. Results reporting

All final reports sent to clients shall state that backup system or referral laboratory was used for testing the samples. This can be achieved via the use of memos or indicating on the reports.

## 7. Quality Assurance and Quality Control

Thorough evaluation process, thorough monitoring of selected referral labs or system, appropriate documentation and record keeping.

## 8. Records

- Method and Instrument Validation and Comparison Records.
- Back-up Plan list.
- Corrective action and problem report forms.
- Evaluation and Selection Criteria Reports.
- Conditions of Service for referred work.

## 9. Reference

- XYZ Quality Manual Current Version.
- ISO/IEC 17025 International Standard.

## Appendix – Evaluation and Selection Criteria Form

### Revision History:

Revision Level	Revision Date	Revised By	Brief description of revision

(Format)

## Annexure E2 – Evaluation and Selection Criteria Format: Sample

Evaluation done by: .....

Date: .....

Please attach supporting documents as and when necessary

### **A. Laboratory's Capabilities** (maximum 25 points)

#### **1. Background (1-5 points): --**

- a) Does the laboratory have a reputation for high quality and integrity? .....
- b) How long has the lab been in business (e.g. 5 years, 10, more)? .....
- c) What are clients' general observations regarding the lab's services? .....

#### **2. Experience and references (1-5 points): --**

- a) Has the laboratory provided a list of References? .....
- b) How long have clients been served by the lab? .....

#### **3. Quality Management (1-5 points): --**

- a) Does the lab have a QMS? .....
- b) Does the Lab have a Quality Assurance Plan? .....
- c) Is the Laboratory accredited? Is the documentation available? .....

#### **4. Equipment (lab and data handling) (1-5 points): --**

- a) Is the testing equipment adequate for the scope and volume of services offered?
- b) Is there adequate backup in the event of equipment failure? .....
- c) Does the automated data processing equipment capability appear to be adequate for the scope of the work contract (e.g., direct transmissions, online result reporting)?

#### **5. Accreditation and certifications (1-5 points): --**

Total points for section A: .....

Document where the lab was lacking: .....

### **B. Quality assurance** (maximum 25 points; assign 1-5 points for each question)

- a) Is a written, organized, comprehensive quality control (QC) program in place? --
  - b) Is there a process for remedial action when QC tolerance limits are exceeded? --
  - c) Is an ongoing monitoring program in place to review, detect, and correct system errors?
  - d) Is a copy of proficiency testing (PT) results available for at least the previous 24 months, and for deficiencies noted, were appropriate and timely corrective actions documented?
- Attach copies --

- e) Does the laboratory have a written, clearly defined protocol for notifying clients of critical values?

Total points for section B: \_\_\_\_\_

Document where the lab was lacking: .....

**C. Efficiency of referral services** (maximum 25 points; assign 1-5 points for each question)

- a) Does the lab offer a sufficient range of services to satisfy our needs? --  
b) Does the lab provide a written TAT for each test performed, and does the TAT meet our needs? --  
c) Are data elements for each test complete? --  
d) Methods used for testing/reporting results --  
e) Specimen handling policies/procedures. Includes clearly defined, comprehensive instructions for preparing specimens as well as criteria for rejecting unsatisfactory specimens --  
f) Equipment maintenance policies --  
g) Information and data handling policies/procedures --  
h) Printing of reports via computer or printer in participating lab (is printer provided?) --  
i) Adequate specimen pick-up service?  
j) Does the lab have a written protocol for reviewing test reports for possible errors? --  
k) Is the test report format clear and can it be read easily? --  
l) Does the lab provide client consultation services on a daily basis, including client services, technical advice, and medical consultation concerning appropriate test ordering and interpretation of results? --

Total points for section C: --

Document where the lab was lacking: .....

**D. Personnel** (maximum 30 points; assign 0-5 points for each question)

- a) Percentage of technologists to technicians: [is greater than] 75% (5 points); 50% (3 points); [is less than] 25% (0 points) --  
b) Does the lab employ a qualified supervisor during all hours of operation? Yes (5 points); No (0 points) --  
c) Are specific staff members assigned to assist us at all times? Yes (5 points); No (0 points)  
d) Are doctoral-level scientists or pathologists available for consultation? Yes (5 points); No (0 points)  
e) Does the technical staff have expertise in all areas required? Yes (5 points); No (0 points)  
f) Does the technical staff receive continuing education on an ongoing basis and is this education documented? Yes (5 points); No (0 points) --

Total points for section D: --

Document where the lab was lacking: .....

**E. Results for method and instrument comparison studies:** Acceptable/Unacceptable

Evaluator's comments: .....

Lab Manager Comments: .....

Lab Approved/Not Approved: .....

Signature: ..... Date: .....

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Annexure F1: Format for Supplier Selection and Evaluation (Equipment): Sample

Equipment Assessment	Equipment 1	Equipment 2	Equipment 3	Total Marks	Comments	Evaluation by
Equipment Name/ID						
Name Of Service provider						
1 Promptness of service (If downtime monitoring is available, pl mention)						
2 Remote support						
3 Onsite support						
4 CMC availability						
5 Availability of spare parts						
6 Provision of Staff Training						
Change to the approved supplier(Yes/No)If yes, evaluate the new supplier						
Total Marks						
Grading						
Sign by QM						

Grades from 1 to 5: 1 for poor performance, 2 average, 3 good, 4 very good, 5 excellent

Maximum marks possible 25.The policy has to be defined by the lab for cut off. This is to be defined in the QSP

Annexure F2: Format for supplier selection and evaluation (Reagent): Sample

	Evaluation point		Supp 1	Supp2	Supp3	Total Marks	Comments	Evaluation by
	Change to the approved supplier (YES/NO)If yes, evaluate the new supplier							
1	Level	L1 :						
		L2 : 8						
		L3 : 6						
2	Maintaining Rate Contract							
3	Maintaining Cold chain							
4	Condition of goods on reception							
5	Promptness of Delivery							
6	Maintaining Steady Lots							
7	Providing Long Expiry							
8	SOS supply							
9	Replacing failed “Acceptance testing” goods							
10	Change to the approved supplier). If yes, evaluate the new supplier		Y/N	Y/N	Y/N			
	Total							
	Grading							
	Sign by QM							

Grades from 1 to 5. 1 for poor performance, 2 average, 3 good, 4 very good, 5 excellent.

Maximum marks 50. The policy has to be defined by the lab for cut off. This is to be defined in the QSP

Annexure G: Format for Feedback and Complaint Resolution: Sample

Front Side (Feedback)				
Date				
Time				
Name (Not Mandatory)				
Phone No				
Adress				
Age/Sex				
Feedback Form				
1- Information and guidance at reception/registration				
<b>Good</b>	<b>Satisfactory</b>	<b>Unsatisfactory</b>	<b>Poor</b>	
2- Time taken for registration /Total waiting Time				
<b>Good</b>	<b>Satisfactory</b>	<b>Unsatisfactory</b>	<b>Poor</b>	
<b>Good</b>	<b>Satisfactory</b>	<b>Unsatisfactory</b>	<b>Poor</b>	
4-How do you rate the staff behaviour?				
<b>Good</b>	<b>Satisfactory</b>	<b>Unsatisfactory</b>	<b>Poor</b>	
5- Hygiene and cleanliness in the lab				
<b>Good</b>	<b>Satisfactory</b>	<b>Unsatisfactory</b>	<b>Poor</b>	
6- Are you satisfied with the report?				
Yes	No	If no, why		
7-Was the report delivered on time?				
Yes		No		
Note- We are working to improve accessibility at the Lab. Your feedback is important to us, Please help us continue improve accessibility at the lab sothat we can better serve our patients.				
Signature of Patient				
Signature of QM				



Back Side (Complaints)	
Date	
Time	
Name (Not Mandatory)	
Phone No	
Address	
Age/Sex	
Complaint	
Immediate Action	
RCA	
Resolution of the Complaint	
Time taken for resolution	
Preventive Action	
Signature of QM	

Note: Please translate into local language. Make available at all customer interfaces.

Annexure H: Format for NCE/Incident/ Occurrence/Accident reporting and immediate, corrective and preventive action taken: Sample

Date/Time	
Non-Conforming Event / Incident / Accident	
Clause No (ISO 15189)	
Department	
Reported by	
Immediate Action	
Corrective Action	
RCA (Root cause analysis)	
Preventive Action	
Time Taken for resolution	
Sign QM	
Sign of Lab Director	

1. NCE - Any event not in conformance to the stated policies & procedures of the lab. e.g. Non fasting sample accepted for a lipid profile test, lack of Preventive Maintenance
2. Incidents - small occurrences/ mishaps e.g. Needle stick injuries, Spills
3. Accidents - larger occurrences e.g. Fire

*Note: These formats should be available at all points of Laboratory services from Registration to sample disposal. In all the above occurrences, the full follow up (including immediate response, CAPA) should be documented and filed*

### Annexure I Format for Records of Internal / External Audit: Sample

Type of Audit									
Name of Auditor									
Checklist No (By Which conducted the audit)									
Date of Audit									
S. No	NC. No	Type	Cause	Department (Area)	NCE in Detail	Responsibility	Time for closing the NC	Corrective action	Attached document

### Annexure II: Format for assessing and managing risk: Sample

S.No	Date	Place/Section	Process involved (Pre – examination/Examination/Post Examination)	Tool used (Maintain evidence)	Severity	Occurrence	Type of risk (Mild/Moderate/ Severe)	Person Assessing the risk	Action Taken	Signature Of QM	Review of action taken - approval by	Sign of Lab Director

## Annexure J2: CLSI EP23 Risk Assessment Matrix

CLSI EP-23 document: **Risk Matrix**

Probability of harm (Frequency)	Severity of harm (Impact)				
	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	U	U	U	U	U
Probable	A	U	U	U	U
Occasional	A	A	A	U	U
Remote	A	A	A	U	U
Improbable	A	A	A	A	A

A = Acceptable risk

U = Unacceptable risk

Annexure K:Format for recording Management Review Meeting reports: Sample

Sl. No		
Subject	QMS improvement	
	Improvement of services to users	
	Resource Needs	
Responsibility		
Action Plan		
Date of completion		