

LABS FOR LIFE PROJECT
DOCUMENTATION & RECORD MANAGEMENT
FOR LABORATORY QUALITY MANAGEMENT SYSTEM
TRAINING MODULE

2016

Ministry of Health & Family Welfare
Government of India



सत्यमेव जयते

Government of India

Ministry of Health & Family Welfare

Department of Health & Family Welfare

Dr. Naresh Goel

Dy. Director General, NACO &
Coordinator for L4L project.

Tel. : 91-11-23351719, 43509917

Fax : 91-11-23731746

E-mail : labsforlife.mohfw@gmail.com

Labs for Life Project

(A Partnership Project with CDC)

9th Floor, Chandralok Building
36, Janpath, New Delhi-110001

FOREWORD

Documentation constitutes an essential part of the Quality Management System. A good documentation practice reflects the professionalism of a laboratory. It not only guides one through every task to be performed systematically, but also keeps track of all the activities completed.

A well-documented QMS defines its own establishment through the commitment of the higher management. In the public health system, this throws light on the need for the state, district and institutional authorities to guarantee the quality of laboratory activities. Organizations are encouraged to express this through a Quality Policy and a Quality Manual. A well-documented laboratory QMS also defines all the technical aspects without ambiguity, so that the bench-level worker is given the directions for efficient implementation of standard practices. Finally, a well-documented Quality Management System produces evidence of all its activities to enable its continual improvement.

In today's healthcare scenario, in which the patient is also a knowledgeable customer with rights, it becomes very important that an organization is accountable for every service rendered. This is where a good documentation system comes into place. "Do What you Wrote and Write What You are Doing" can be an important guiding principle to set a stage for a more organized health care structure than existing scenario in which different institutions follow varying degrees of discipline in record keeping.

This module on Documentation is a fruit of hard labour wherein many experts have come together to create a very comprehensive text on how to begin with documentation in a healthcare setting. Standard ISO: 15189 is the backbone of this document along with other referenced guidelines which have been used worldwide to develop a Quality Management System in a laboratory. I hope this module proves useful to all who want to improve the quality of their labs and thereby improve patient outcomes.


(Dr. Naresh Goel)

Acknowledgement

This module on “Documentation and Record Management” for Laboratory Quality Management System has been developed by the Labs for Life Project of Ministry of Health and Family Welfare, Government of India, for providing guidance in developing a well-documented Quality Management System in Public Health Laboratories in India.

Dr. Anu George is acknowledged for the technical contribution and collation of all available information related to the subject. Other experts who have put their best efforts in drafting and finalization of this module are also sincerely acknowledged.

Sincere gratitude is expressed to the U.S. Centers for Disease Control and Prevention-Division of Global HIV/TB (CDC/DGHT), India Office, its implementing partner Christian Medical Association of India (CMAI) and Becton Dickinson, collaborating partner for Labs for Life Project for providing technical assistance, guidance and support in finalization of this module.

List of Contributors

Core Committee Members

- Shri N.S.Kang, AS& DG, MoHFW- Chairperson
- Dr.Naresh Goel, DDG, NACO-Coordinator
- Dr. Srinivasan Venkatesh, Director, NCDC
- Dr. Damodar Bachani, Deputy Commissioner, NCD
- Dr. A.S.Chauhan, Director Finance, NACO
- Dr. J.N. Srivastava, Advisor, NHSRC
- Ms. Capt. Kapil Chaudhary, Dy. Secretary NHM
- Dr. Pauline Harvey, Director CDC-DGHT
- Dr. Sunita Upadhyaya, Senior Laboratory Advisor, CDC-DGHT
- Dr. Adarsh Pal Singh, Regional Director Global Health (Asia Pacific), BD

Technical Writing/Editorial Members

1.	Dr. Naresh Goel	:	DDG, NACO & Project Co-ordinator L4L, MoHFW
2.	Dr. Anu George	:	Technical Manager, Labs for Life Project
3.	Dr. Sunita Upadhyaya	:	Senior Laboratory Advisor, CDC-DGHT
4.	Dr. Sarika Mohan	:	Senior Scientific Advisor, CMAI
5.	Dr. Edwin Sam	:	Technical Advisor, Strategic Information, CMAI
6.	Ms. Chhavi Garg	:	Project Associate, Labs for Life Project

Table of Contents

List of Tables

List of Formats

List of Figures

IMPORTANCE OF DOCUMENTATION

• Background	iv
• Purpose and Objectives	iv
• Target Audience	iv
• Materials and Methods	vi
• How to use this Manual	vii

CHAPTER 1: DOCUMENTS AND RECORDS: OVERVIEW

1.1 Learning Objectives	01
1.2 Why to Document?	02
1.3 Major Advantages of Keeping Documents and Records	03
1.4 How to Document?	03
1.5 Difference between Documents and Records	04

CHAPTER 2: DOCUMENTS AND RECORDS FOR A QUALITY MANAGEMENT SYSTEM

2.1 Learning Objectives	06
2.2 Level 1: Strategic Level- Policies	08
2.3 Level 2: Tactical Level -Processes, Process Approach and Procedures	08
2.3.1 Processes	08
2.3.2 Process Approach	09
2.3.3 Procedures	09
2.4 Level 3: Operative Level-Formats and Records	10
2.4.1 Importance of Formats	10
2.4.2 Importance of Records	11
2.5 Documentation Requirements for a QMS and Document Hierarchy: Specifics	11

CHAPTER 3: DEVELOPING A LAB DOCUMENTATION SYSTEM

3.1 Learning Objectives	12
3.2 Developing a Quality Policy (ISO 15189 Clause 4.1.2.3)	13

3.3	Quality Objectives and Planning (ISO 15189 Clause 4.1.2.4)	13
3.3.1	Setting Quality Objectives	13
3.3.2	Monitoring Quality Objectives	14
3.4	Writing a Quality Manual (ISO 15189 Clause 4.2.2.2)	15
3.5	Mapping and Developing Processes	17
3.6	Procedures	18
3.6.1	Writing Quality System procedures or Mandatory Procedures	18
3.6.2	Writing Standard Operating Procedure (SOP)	19
3.6.3	Making Job Aids/ Bench Aid/ Work Desk Instructions / Work Instructions	21
3.7	Formats and Records	23
3.7.1	Identifying the List of Records Required in a Lab	23
3.7.2	Designing Formats	25
3.7.3	List of Records Mandated by ISO 15189	25
3.7.4	Recap: Interrelationship of a Policy, Process, Procedure, Formats and Records	28
CHAPTER 4: DOCUMENT CONTROL: MAINTAINING THE INVENTORY OF DOCUMENTS		
4.1	Learning Objectives	30
4.2	Purpose of Document Control	31
4.3	Examples of Controlled Documents	31
4.4	Elements of Document Control System	31
4.5	Developing a Document Control System	32
4.5.1	Standardizing the Format	32
4.5.2	A Process for Formal Approval, Updating and Revising Laboratory Documents and a Distribution Plan or List.	33
4.5.3	Assuring Accessibility	34
4.5.4	Preventing Use of Obsolete Documents	34
4.5.5	Archival of Documents	34
4.5.6	Creating a Master Log	36
4.5.7	Developing an Audit Trail	36
4.6	Implementing a New Document Control System	36
4.7	Common Problems	37
BIBLIOGRAPHY		38
ANNEXURES		39
GLOSSARY		62
ABBREVIATIONS		65

List of Tables

Table 1.1 Comparison of Documentation Requirements between 1SO 9001 and ISO15189	: 02
Table 1.2 Differences between Documents and Records	: 05
Table 2.1 Difference between Process and Procedures	: 09
Table 3.1 Procedures with Mandatory Documentation as per ISO 15189	: 18
Table 3.2 Inter-relationship of a Policy, Process, Procedure, Formats, Records	: 29

List of Formats

Format 1 Sample Master log 1 (As per ISO Clauses)	: 24
Format 2 Machine Downtime Monitoring Format	: 25
Format 3a Complete Standardized Headers	: 32
Format 3b Reduced Standardized Headers	: 33
Format 4 Document Amendment Format	: 34
Format 5 Distribution List Format	: 34
Format 6 Sample Master Log 2 (As per Lab Document Identity)	: 36

List of Figures

Figure 1 Document Hierarchy Concept Overview	: 07
Figure 2 Relation between Policies, Processes, and Procedures	: 10
Figure 3 Document Hierarchy Specifics: Lab QMS	: 11
Figure 4 Quality Policy, Objectives, and Indicators; Interrelationship	: 14
Figure 5 Record of Permission for Bio-Medical Waste Generation. Retention Period: Till next Renewal (or as defined by the lab)	: 26
Figure 6 EQAS report Biochemistry Retention Period 1 year(or as defined by the lab)	: 27
Figure 7 Machine Printout– CBC, Retention Time 1 week (or as defined by the lab)	: 27

Documentation & Record Management



BACKGROUND

A documented Quality Management System not only integrates the various internal processes within the organization but also clearly expresses the laboratory's process of establishing the QMS, methods for implementation and maintenance of the QMS. A complete Laboratory Quality Management System must meet the ISO-9001 Documentation requirements and as stated in ISO 15189.

Organizations are allowed flexibility in the way it chooses to document its Quality Management System (QMS), enabling each individual organization to develop a minimum amount of documentation to demonstrate the planning, operation and control of its processes as well as implementation and continual improvement of the effectiveness of its QMS.

The following are some of the main objectives of documentation in an organization:

- i. Communication of information - as a tool for information transmission and communication. The type and extent of documentation will depend on the nature of the organization's processes, the degree of formality of communication systems and level of communication skills within the organization and organizational culture.
- ii. Evidence of conformity - provision of evidence to confirm whether activities have been carried out as planned.
- iii. Knowledge sharing - to disseminate and preserve the organization's experiences.

A good documentation system seeks to ensure that all requirements have been documented within the management and technical systems, outline performance processes to the quality system requirements, produce records or evidence that the system requirements have been met, measure, monitor and report the extent of compliance with these performance procedures. It should also confirm and document that employees receive applicable training in the quality system requirements, show evidence of continually monitoring and analysing changes, execution of audits and analysis of the system processes and of correcting them when necessary to include processes that will help to continually improve the quality system.

“

Documentation is the Systematic Handling of
Organizational Knowledge in
Conformity with the ISO Standard

”

PURPOSE AND OBJECTIVES

This manual defines methods of documentation as defined in the ISO: 15189, ISO 9001 and CLSI guidelines. This manual has been prepared for use in the Training for the Labs for Life project to:

- ◆ Understand the need for documentation and explain the important steps, or elements, of a laboratory document management system
- ◆ Understand the good documentation practices as defined under the ISO standard and CLSI guidelines
- ◆ Understand the document hierarchy in QMS and the role of each level
- ◆ Explain the difference between documents and records
- ◆ Understand document identifiers
- ◆ Learn how to implement a document control system
- ◆ Understand how to write Quality Policy
- ◆ Outline the contents of a Quality Manual
- ◆ Outline the content of Quality System Procedures
- ◆ Outline the content of the Standard Operating Procedure
- ◆ Understand the need for formats
- ◆ Understand designing formats
- ◆ Describe methods and tools to store documents and records

TARGET AUDIENCE

- ◆ Laboratory Managers
- ◆ Technical and Supervisory staff
- ◆ Lab Technicians

MATERIALS AND METHODS

- ◆ Trainer's manual
- ◆ Presentations
- ◆ Hands on activities

HOW TO USE THIS MANUAL

Chapter 1: Talks about the major advantages of keeping documents and records. It also addresses the question of why and how to document and explains the difference between documents and records.

Chapter 2: Talks about the structure of the documentation needed for a Quality Management System, illustrating the hierarchies of documents. The term **Document Hierarchy** denotes the structure of documentation of an organization. The hierarchy is variably described in different interpretations. However, essentially it should enable the understanding of the following at each level regardless of the list of documents included at that level:

- a) The function
- b) The responsibility for creating and maintaining the document.

This module describes the hierarchy **with three levels** as follows:

Level - 1 (*Strategic Documents*): Documents for establishing a documented QMS. These include Policies, comprising the apex or Quality Policy and the policy manual; the Quality Manual.

Level - 2 (*Tactical Documents*): Documents for implementing a QMS that include; Processes and Procedures; comprising Quality System Procedures, Standard Operating Procedures and Job Aids/ Bench - Aids/ Work Desk Instructions.

Level - 3 (*Operative Documents*): Documents for maintaining a QMS; which include the Formats and Records.

Chapter 3: Explains the developing of a Laboratory Documentation System as per ISO 15189 which includes developing a Quality Policy as per Clause 4.1.2.3, setting and monitoring Quality Objectives as per Clause 4.1.2.4, writing a Quality Manual as per Clause 4.2.2.2, Mapping and Developing Processes and Procedures including Quality System procedures or Mandatory Procedures (multiple clauses) , Standard Operating Procedure and Job Aids as per clause 5.5.3. It also throws light on the understanding and compiling the list of formats required in a lab, designing formats, list of records mandated by 4.13 and other clauses and finally, the retention of records as per NABL 112. The annexures illustrate each of these documents.

Chapter 4: Defines the document control process as per ISO-15189 clause 4.3 for maintaining the inventory of documents. It explains the purpose of document control, examples of controlled documents and elements of document control system and gives suggestions on developing and implementing a new document control system. It also illustrates a few common problems in document control.

Chapter 1

Documents and Records: Overview

1.1 Learning Objectives:

At the end of this chapter, the learners should be able to understand the

- Importance of a documentation system
- Overview of document hierarchy
- Difference between documents and records



A document is defined as ‘information (meaningful data) and its supporting medium. In simple terms, we can say that a document provides guidance and/or direction for performing work, making a decision or rendering judgment.

A record is defined as a document stating results achieved or providing evidence of activities performed. Records are special types of documents. The table below shows some comparisons of documentation requirement between ISO 9001 and ISO 15189.

Table 1: Comparison of documentation requirements between ISO 9001 and ISO 15189

ISO 9001	ISO 15189
4.2.3 Control of Documents	4.3 Document Control
4.2.4 Control of Records	4.13 Control of records 5.1.9 Personnel records 5.3.1.7 Equipment records 5.3.2.7 Reagents and consumable records 5.8.5 Report content

1.2 Why to Document ?

Before deciding to document anything, there is something more important to consider. The transmission of information may be more important rather than its documentation and therefore firstly determine the best method of transmitting the information.

There are several choices depending on the complexity of the operation:

- Convey it verbally - suitable for instructions intended for immediate action. But verbal instructions alone may not be heard, may be misunderstood, are quickly forgotten, and are difficult to follow
- Convey it so that it is observed visually - suitable for warnings (Signage)
- Convey it through education and examples - suitable for values, beliefs and principles
- Communicate it through training - suitable for methods and routines
- Communicate it through documents - suitable for information that needs to be referred to when performing complex tasks.

Documents are the best communicators of the quality system. All policies, processes, and procedures must be written so that everyone will know the proper procedures and can carry them out. Everyone, both inside and outside the laboratory, must know what is being done, and what should be done at each step. Therefore, all of the guidelines must be written so that they are available and accessible to all who need them. Documents are a reflection of the laboratory’s organization and its quality management. A well-managed laboratory will always have a strong set of documents to guide its work.



1.3 Major advantages of documentation are to,

- Find the information wherever it is needed.
- (Each laboratory staff member being able to) Access, understand and be able to describe the activities for each Quality System Essential that pertains to his or her job responsibilities.
- Communicate requirements, intentions, instructions, methods and results effectively
- Convert solved problems into recorded knowledge so as to avoid having to solve them repeatedly
- Provide freedom for management and staff to maximize their contribution to the services
- Make the service system centered and release it from reliance on particular individuals for its effectiveness
- Provide legitimacy and authority for the actions and decisions needed
- Make responsibility clear and to create the conditions for self-control
- Provide coordination of inter-departmental action
- Provide consistency and predictability in carrying out repetitive tasks
- Provide training and reference material for new and existing staff
- Provide evidence to those concerned about your intentions and your actions
- Provide a basis for studying existing work practices and identifying opportunities for improvement
- Demonstrate after an incident the precautions that were taken or which should have been taken to prevent it or minimize its occurrence

1.4 How to Document ?

Considering the complexity of the tasks involved in a clinical laboratory, to enable a successful QMS, ISO 15189 recommends several levels of documentation.

- Documenting the quality policy and objectives: The management commitment to quality as per ISO15189 and applicable national and international standards and guidelines should be stated.
- Documenting all policies of the lab as per ISO 15189 requirement in a Quality Manual
- Documenting the Quality Management System Procedures
- Documenting the information needed for the effective operation and control of procedures- Standard Operating Procedures (SOPs) Documenting bench-aids and quick reference instructions from SOPs
- Documenting records i.e. the evidence produced by the activities of the QMS



Documents: Information used to support effective and efficient organizational operation.

A document consists of any information used to run organizations. Documents originate in the planning phase of the Plan, Do, Check act, cycle of the process approach. Since many documents are “planning material” defined in the **Plan** Phase, they are subject to change as we obtain more information in the **Do** phase and compare those records in the **Check** phase, to the original plan. Documents thus are live entities subject to amendments as and when needed.



Records: Evidence about a past event.

A record is generated in the “**Do**” phase of PDCA. Records consist of any data you collect during the operation of your QMS. Records are facts and should not change. The records of **Check** and **Act** phases also need documentation to track the amendment of processes. Records, thus are dead documents which cannot be changed.

1.5 Difference between Documents and Records

Recap!!

Documents

- Communicate information to all personnel who need it including lab staff, nurses, users of the lab and lab management
- Need to be updated and maintained
- Must be changed when policy, process or procedure changes
- Establish formats for recording and reporting information by standardized formats

Examples are Quality Manual, SOPs, Bench Aids

Records

- Are collected/ captured information produced by the laboratory in the process of performing and reporting tests
- Become a record once used to document elicited data
- Need to be easily retrieved or accessed
- Contain information that is permanent and cannot be edited
- Need to be retained as per standard guidelines and lab policy



Table 1.2: Differences between Documents and Records

Document	Record
Live	Dead
How to carry out an activity	How the activity was carried out and the results
Subject to change	Not subject to change
Approved and issued (or released) by designated authorities before issue	Approved after the activity is over by designated authorities
Retention period of generally are not defined as these are live	Retention period has to be clearly defined as per local regulations

“

**Stressed about the word “Documentation”?
Relax!!**

**Good documentation practices will serve you well!
It’s a great investment!!**

”



Chapter 2

Documents and Records for a Quality Management System

2.1 Learning Objectives:

At the end of this chapter, the learners should be able to understand

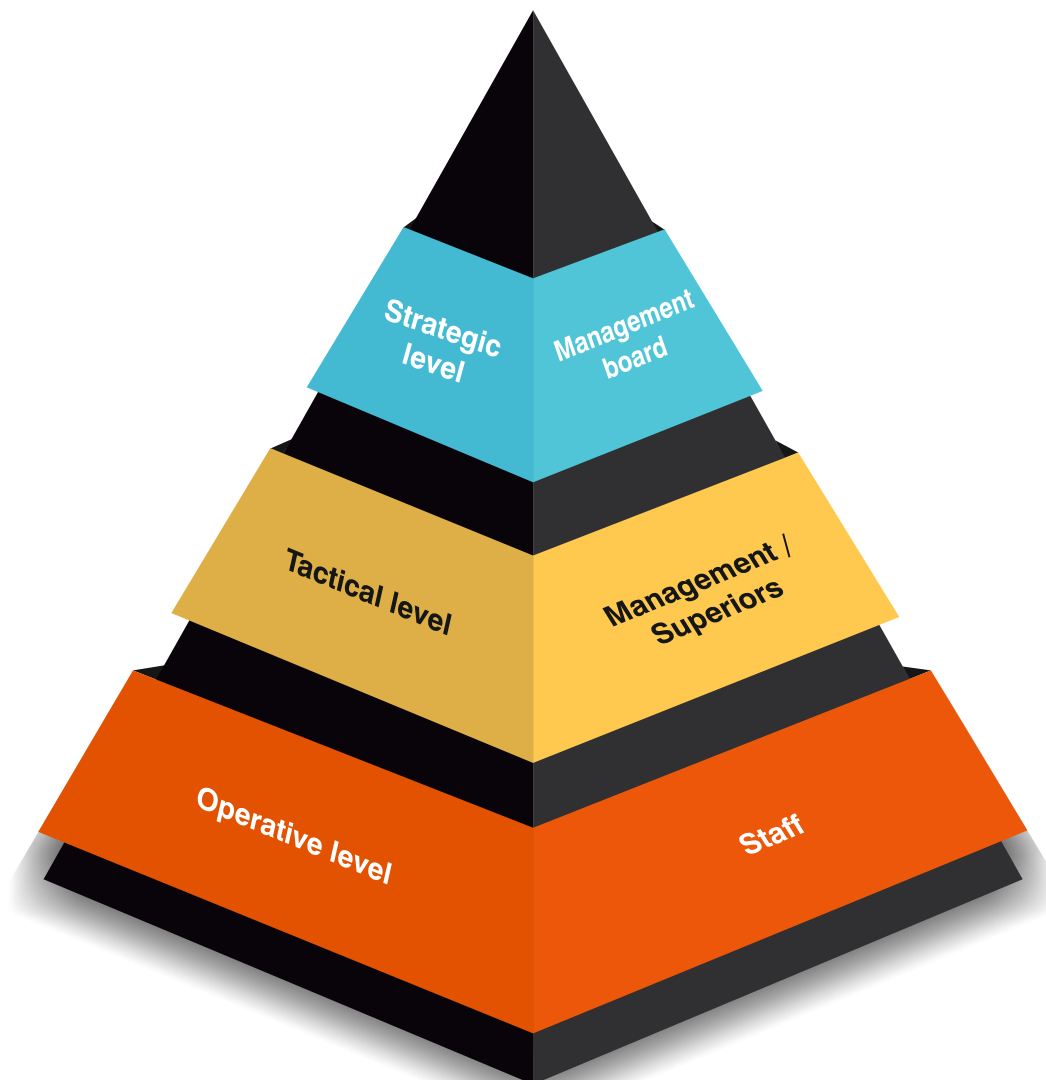
- Level 1 Documents: Documented Information of Establishing a QMS
- Level 2 Documents: Documented Information for Implementing a QMS
- Level 3 Documents: Documented Information for Maintaining a QMS
- The Document Hierarchy in a Quality Management System

ISO 9001
requires a

“Documented Quality Management System”;
Not a “System of Documents”.

Documents include all the **written policies, processes, and procedures** of an organization. It is important to understand each of these elements and how they relate.

Figure 1 : Document Hierarchy Concept Overview



2.2 LEVEL 1: Strategic Level - Policies

Documented Information of Establishing a QMS

A policy is “a documented statement of overall intentions and direction defined by those in the organization and endorsed by management”.

**A policy is a commitment,
formally stated by the top management.**

Quality Manual including Quality Policy

Policies give a broad and general direction to the quality system. Policies provide guidance on “what to do”, in a broad and general way, **state** the organizational mission, goals, and purpose. They also **serve** as the framework for the quality system, and should always be specified in the quality manual.

Although there are certain national policies/ statutory requirements that affect laboratory operations, each laboratory will develop policies specific to its own operations.

2.3 LEVEL 2: Tactical Level - Processes, Process Approach and Procedures

Documented Information of Implementing a QMS

2.3.1 Processes are the steps involved in carrying out quality policies; “set of interrelated or interacting activities that transform inputs into outputs.” Thus, any activity or set of activities that uses resources (people, machines, etc.) to transform inputs into outputs can be considered a process. Processes must have defined (but not necessarily measurable) objective(s), input(s), output(s), activities, and resources. You should be able to answer these when defining a process:

- I. Activities:
What are the basic activities carried out in your department?
Can you explain to me your operations here?
- II. Inputs/Resources:
What information and resources do you need to start your work?
Where does it come from?
- III. Outputs:
Who receives the result of your work?
How do you know if you've done your job correctly? (meet objectives)

Every organization is made up of a series of interacting processes. A process expresses “**how it happens here**”. Processes can be represented in a flow chart, with a series of steps to indicate how events should occur over a period.

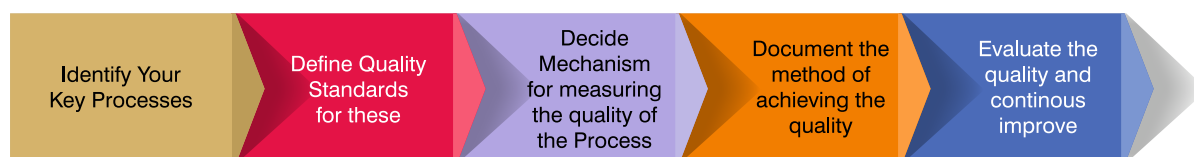
2.3.2 Process Approach

The process approach considers the interaction between different processes, and the inputs and outputs that tie these processes together. The output of one process becomes the input of another.

Some examples of laboratory inputs include test requests and samples; the pre-analytical process. The output of this process becomes input for the analytical process, the output of which in turn will become inputs for the reporting process and so on. Using these examples, one process might be how to transform a test request (input) into a report (output). Procurement, Inventory Control, Bio-medical waste management, recruitment of staff and so on, are all examples of processes occurring in a lab.

While defining a process, five important aspects need to be considered

1. First, you identify your key processes with activities and sub-activities of each
2. Second, you define quality standards for those processes.
3. Third, you decide how process quality will be measured.
4. Fourth, you document your approach to achieving the desired quality, as determined by your measurements.
5. Fifth, you evaluate your quality and continuously improve.



A process is not a document. However, processes may be depicted as flowcharts for ease of understanding



2.3.3 Procedures

Procedures are the **specific activity/part of a process**. A few examples: contained within the pre-examination process is the performance of a specific aspect like sample collection, a procedure. The performance of a test is a procedure. Contained in the inventory control process are procedures like indenting, stock verification etc.

Thus a procedure explains “**how to do it**”, and shows step-by-step instructions that laboratory staff should meticulously follow for each activity.

Table 2.1: Difference between Process and Procedures

Processes	Procedures
Processes are driven by achievement of the desired outcome	Procedures are driven by completion of the task
Processes are operated	Procedures are implemented
Process stages are completed by different people with the same objectives - departments do not matter	Procedures steps are completed by different people in different departments with different objectives
Processes flow to conclusion	Procedures are discontinuous
Processes focus on satisfying the user or patient	Procedures focus on satisfying the rules
Processes transform inputs into outputs through use of resources	Procedures define the sequence of steps to execute a task



A) The term **Standard Operating Procedure (SOP)** is often used to indicate these detailed instructions on how to do it.

B) **Quality System Procedures** are also procedural documents.

These pertain to parts of certain processes that require clarity and hence need detailed definitions. These are described in the following chapters.

C) **Job Aids/ Bench-Aids/ Work Desk Instructions**

These are shortened versions of SOPs that can be posted at the bench for easy reference on performing a procedure. They are meant to supplement, not replace, the SOPs.

A good way to represent the relationship of policies, processes, and procedures is as a tree. The policies are represented by the roots, and they form the base for all the other parts. The processes can be viewed as the trunk of the tree, representing a series of steps or flow of actions through the laboratory. The leaves of the tree can be thought of as the procedures; there will be many procedures in the laboratory for accomplishing the activities or the work.

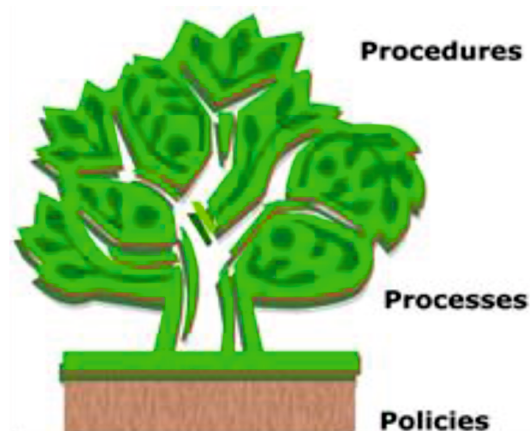


Figure 2: Relation between Policies, Processes & Procedures

2.4 LEVEL 3: Operative Level - Formats and Records

Documented Information of Maintaining a QMS

2.4.1 Importance of Formats

Quality Management System requires several formats to capture data, information, and results. Designing formats for this as per requirement of the activity is an important aspect of QMS activities. Forms/ formats thus designed are blank pages/computer screens/ labels, etc. on which data is recorded.

Forms / Formats may be amended as per requirement of activity. Date and time of these amendments along with the details of the person making the amendments should be documented

Once data is entered on a form or format, it becomes a record.

2.4.2 Importance of Records

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

- Continuous monitoring
- Tracking of samples

- Evaluating problems—well-kept equipment records will allow for thorough evaluation of any problems that arise
- Management—good records serve as a critical management tool

Never change a record. If new information needs to be added to a record, it should be noted as an addition, with a date, and signature or initials.

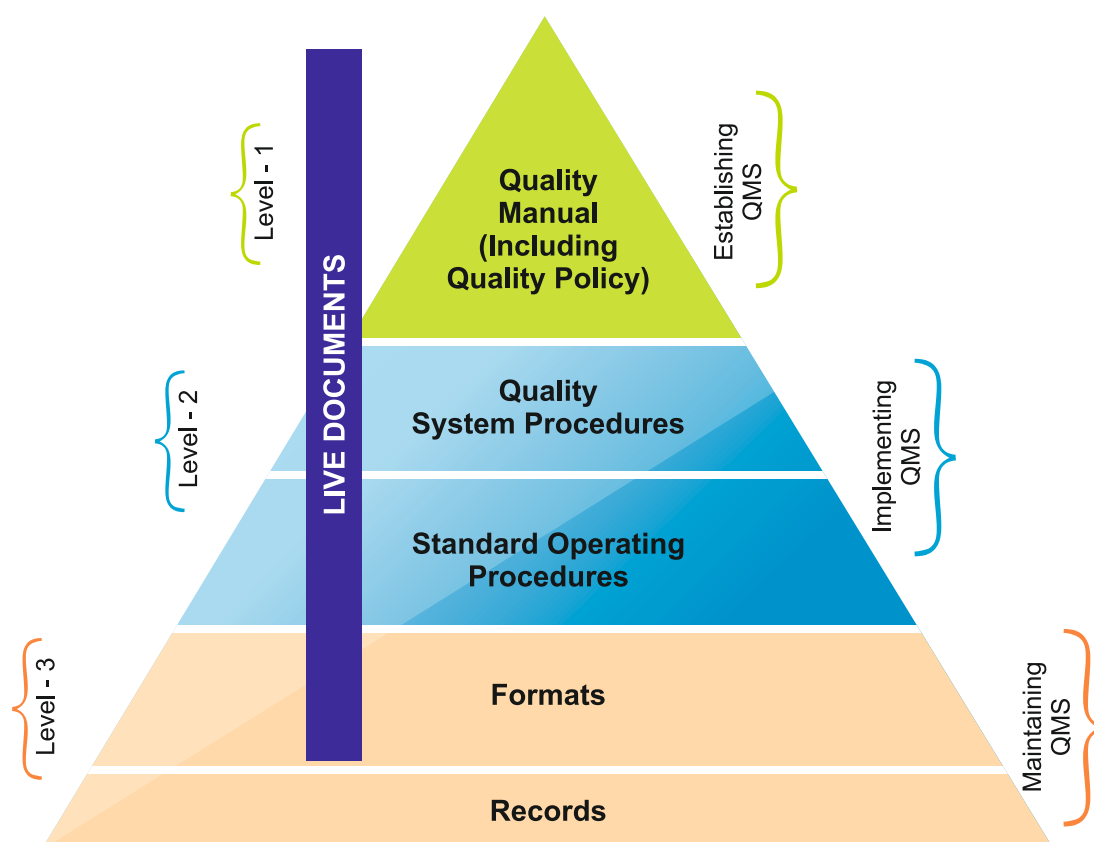
RECAP! And a Bit more!

2.5 Documentation Requirements for a QMS (4.2.2) and Document Hierarchy

Document Hierarchy or Levels in Documenting a QMS

- Policies (Quality Policy, Quality Manual)
- Processes and Procedures (Process Flow charts, Quality System Procedures, Standard Operating Procedures, Bench Aids)
- Formats and Records

Figure 3: Document Hierarchy Specifics : Lab QMS



Chapter 3

Developing a Lab Documentation System as per ISO: 15189

3.1 Learning Objectives:

At the end of this chapter the learners should be able to write and develop

- Quality Policy
- Quality Objectives
- Quality Manual
- Quality System Procedure
- Standard Operating Procedure
- Bench aids/Job Aids
- Formats
- Master List of Documents and Formats

DEVELOPING POLICY DOCUMENTS

3.2 Developing a Quality Policy (ISO: 15189 Clause 4.1.2.3)

The Quality Policy should express the top management's commitment to the implementation and improvement of the lab's Quality Management System in accordance with ISO: 15189

Quality Policy is the “**definition of the intent of the Quality Management system**” as per clause 4.1.2.3 of ISO: 15189 and is a list of statements by the laboratory management. The points to consider while writing a Quality Policy as mandated by the ISO are:

- Stating the purpose of the organization and scope of activities
- Declaring the commitment to good professional practice, allegiance to the International Standard in all activities and continual improvement
- Providing a framework for establishing and reviewing quality objectives
- Ensuring that these statements should be communicated to all staff and should be understood by all
- Ensuring that the policy itself will be reviewed for suitability

A quality policy should express top management's commitment to the quality management system (QMS). It should be based on ISO's quality management principles and should be compatible with other relevant organizational policies and be consistent with its vision and mission.

All the activities undertaken by the laboratory in turn should be consistent with the stated Quality Policy. The Quality Policy should be made aware of all lab staff and should be made available in the local language for better understanding.

Quality Policy development, issue, and authorization are responsibilities of the higher management. In the public health system, the highest supervising authority is strongly encouraged to take this responsibility.

Example of a Quality Policy: Annexure 1

3.3 Quality Objectives and Planning (ISO 15189 Clause 4.1.2.4)

3.3.1 Setting Quality Objectives

The Quality Objectives are set by the top management in discussion with the staff involved in the daily activities and planning of the lab, say, the Lab Directors and HODs.

They should establish and document Quality Objectives. A few points to be kept in mind while defining Quality Objectives are:

- These should be consistent with the Quality Policy
- These should be measurable



- Further planning of the Quality Management System should be based on these objectives
- Should engage all the relevant functions of the lab
- Should involve all the levels of the lab
- Should meet the requirements of the users
- Objectives for improvement activities are to be directed at areas of highest priority based on risk assessments

It will be ideal to use the audit/ assessment findings while setting quality objectives. Areas that need thrust in quality improvement should be chosen as objectives. A measurable Quality Indicator setting to align with this process will enable a good tracking of the improvement process

It is very important to point that people in the organization must be aware of how they contribute to the achievement of the quality objectives. Therefore, employees in the organization must know and understand the specific quality objectives that have been set up for their functions and level, and how they can achieve them. For awareness of quality objectives, specific training sessions may be organized.

The quality objectives should be very simple and direct. Think carefully about the quality objectives set for the organization and the time frame allowed for them to be achieved. Keep in mind that quality objectives must be measurable.

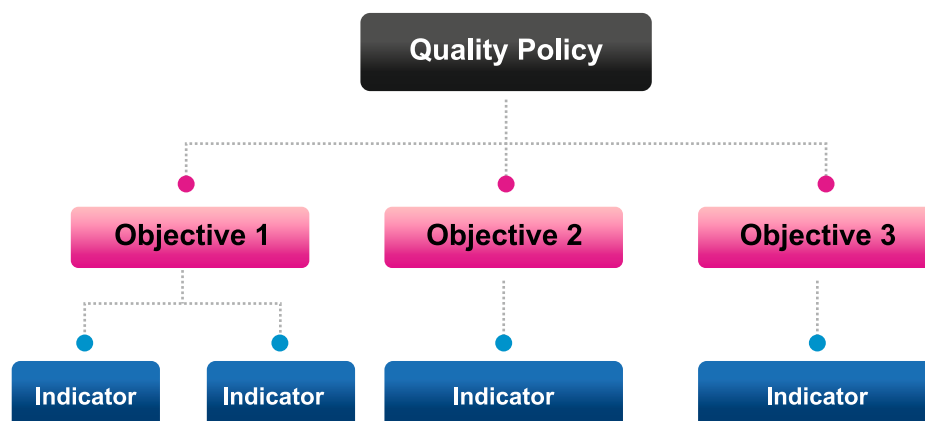
3.3.2 Monitoring Quality Objectives

It is the responsibility of the top management to ensure continuing suitability, adequacy and effectiveness of the QMS and to review the organization's quality management system at planned intervals. The review must include assessing opportunities for improvement and need for changes to the quality management system, including the quality policy and quality objectives.

The management should be able to check that it is achieving the objectives and, if not, what it is going to do about the problem. Monitoring and measurement activities should be planned and carried out to improve the quality of services. Quality objectives may be monitored from the input information received from the following:

- Internal and external audits
- Customer feedback
- Process performance reports using Quality Indicators (some objectives may need multiple indicators to track)

Figure 4: Quality Policy, Objectives and Indicators; Interrelationship



For example, if a laboratory's activities are affected by staff attrition, preventing it may be set as an objective. If the laboratory environment is hard to control, that may be set as an objective and monitored by multiple quality indicators.

Quality Manager (QM) may act as a link person between the top management and the organization. His/her role is very important for maintaining and improving the quality management system in the organization. It is the duty of the QM to report to the top management on the performance of the quality management system and any need for improvement. Accordingly, he/she should monitor quality objectives from the inputs received from various corners.

It is also important to tell employees in the organization regularly how well the specified quality objectives are being met and where improvements are required. Quality objectives must be reviewed and revised from time to time as part of the continual improvement process.

Example for writing a Quality Objectives: Annexure 2

3.4 Writing a Quality Manual (ISO:15189 Clause 4.2.2.2)

This is the apex manual of a lab. Quality Manual serves as a roadmap for meeting QMS requirements by demonstrating management commitment to quality. All procedures in level 2 and 3 of the document hierarchy should be consistent with this. This is the overall guiding document for the quality system and provides the framework for its design and implementation. A laboratory is required to have a Quality Manual for ISO accreditation.

Although the ISO mandates a Quality Manual, the style and structure are not specified leaving considerable flexibility. A laboratory thus, can prepare a manual suited to its needs.



While preparing the manual, each facility should carefully consider involving all the stakeholders. It is essential to involve the management and policy makers, technical and quality managers, heads of departments and relevant technical staff in the drafting as different clauses will require inputs from different personnel.

One can either follow the ISO standard to develop a Quality Manual or the CLSI guidelines. If following the CLSI guidelines, all the 12 Quality System Essentials should be addressed by stating policies for each. For the purpose of NABL accreditation, ISO standard should be used for writing the Quality Manual, stating policies for each clause and sub-clause

For example: The main components to be included in the Quality Manual as per ISO 15189, 4.2.2.2 sub clauses a-f are:

- a) Quality Policy (see above)
- b) A description of the scope of the Quality Management System (Activities of the lab brought under the scope of the QMS)



- c) A presentation of the organization and management and management structure of the laboratory and its place in any parent organization
- d) A description of roles and responsibilities of the laboratory management, including the Lab Director and Quality Manager, for ensuring compliance with the standard
- e) A description of the structure and relationship of the documentation used in QMS
- f) The documented policies established for the QMS and reference to managerial and technical activities to support them

NABL 160, a downloadable document that describes the method of writing a Quality Manual gives the guidelines for the preparation of Quality Manual based on ISO guidelines. The manual talks of both ISO 15189 and 17025 comprehensively. For the purpose of clinical labs, ISO 15189 may be followed. In brief the document states the following:

- There is no required structure or format for a Quality Manual.
- However, any Quality Manual should convey accurately, completely and concisely the Quality Policy Objectives
- Should address and reference to the next level of documentation
- Should address management responsibilities of the laboratory
- One of the methods of assuring that the subject matter is adequately addressed and located would be to align the sections of the Quality Manual to the elements of the ISO: 15189. Other approaches, such as structuring the manual to reflect the nature of the laboratory or nature of work carried out by the laboratory are equally acceptable.
- The NABL 160 is not intended to define a unique structure, format, content or method of presentation for the Quality Manual. Every laboratory should have a unique Quality Manual.
- However, it is recommended that the first few pages of the Quality Manual should address to the sections of general information like title, authority under which it is issued, scope of the Quality Manual, amendment record of the manual, contents of the manual, references to other documents, definitions, abbreviations used, distribution record, brief description of the laboratory and the management system.
- After these pages, there should be a section on 'Quality Policy and Objectives' of the laboratory. The Quality Policy is required to be stated under clause 4.2 of management requirements. It is preferred that it is placed after the introductory pages since this is the basic objective the laboratory's management system is designed to meet.
- The remaining sections of the Quality Manual should describe all applicable elements of the ISO 15189. The description of these sections of the Quality Manual should be in a sequence similar to that of ISO 15189.
- Other sequencing or cross-referencing, as appropriate to the laboratory, is acceptable.

P 13-17 of NABL 160: Annexure 3

As directed by NABL 160, it is useful to follow the clauses of the standard so as to ensure that all elements mandated by the standard has been looked into and addressed.

Also of importance is to describe how related processes occur and make note of all



procedures (SOPs/ QSPs). This may be accomplished by references. Process flow charts in diagrammatic forms, reference to Quality System Procedures will explain the former.

SOPs are integral part of the Quality System, and the Quality Manual should specify that SOPs are developed and make note of all SOPs

The quality manual has to be read and understood by everyone in the lab

Example for Writing a Quality Manual: Annexure 4

DOCUMENTING PROCESSES AND PROCEDURES

3.5 Mapping and Developing Processes

ISO defines processes as a set of interrelated or interacting activities that transform inputs into outputs. Inputs of a process are generally outputs of another process.

Processes describe activities needed to implement the QMS policies and answer the question, “**How is the requirement met in this laboratory/ How is it done here?**”

There are **one or more processes for each QMS policy**. Each process may involve several activities, several people or several categories of people.

As described earlier, it is not necessary that all processes be documented in the text format.

Map out the processes in your lab. Understand the elements included in each process that require more detailed explanation.

For example, Let us take inventory control. This includes elements of clause 4.4; external services and supplies and 5.3; acceptance testing, 5.2; storage facilities and other points that may include state, institution and lab specific activities like indent raising, reorders, annual consumption and so on. All these may be depicted as a process flowchart. Detailed descriptions will be needed for some procedures contained in the process, due to the complexity of the procedure. For instance, selection of reagents; which have to include technical specifications like method and performance characteristics

Process descriptions can be documented in process maps/flow charts or tables. These provide a visual flow/ depiction of how the activities are sequenced. It would be ideal if the chart also says who does each activity.

Few differences between a process and a procedure are as follows

A process involves	Process documents should describe
• Inputs/ Resources • One or more activities • People • Time • Supporting Documents • Generation of documents	• The activities necessary to accomplish the intent of the policy • The correct sequencing of activities for the successful outcome of the process • Which entities or persons are responsible for each activity of the process

Example of a process table/matrix, flow chart: Annexure 5, 6 and 7



3.6 Procedures

Procedures may be those for testing or other specific activities (non-testing).

3.6.1 Quality System procedures or Mandatory Procedures

Procedures that do not directly involve testing are generally termed Quality System Procedures or Mandatory Procedures. Documentation of these procedures have been mandated as they involve many activities and people and it is necessary that each one understands his/her role in the procedure.

Wherever ISO standard indicates that there shall be a documented procedure, (e.g. in 4.4.1; Establishment of service agreements) the procedure should be documented. Even if not required by ISO, it would be ideal to document the complex activities involving multiple steps and people.

Table 3.1: Procedures with Mandatory Documentation as per ISO 15189

Sl. No.	Process	ISO clause
1	Responsibilities, authority, and interrelations	4.1.2.5
2	Document Control	4.3
3	Establishment of service agreements	4.4.1
4	Selection and evaluation of referral labs	4.5.1
5	External Services and Supplies	4.6
6	Resolution of complaints	4.8
7	Identification and control of nonconformities	4.9
8	Control of Records	4.13
9	Personnel Management	5.1
10	Selection, purchase and management of equipment	5.3.1.1
11	Calibration of Equipment	5.3.1.4
12	Preventive maintenance of Equipment	5.3.1.5
13	Reagents and consumables: Reception, storage, acceptance testing, inventory management	5.3.2.1
14	Preexamination activities	5.4.1
15	Collection and Handling of samples	5.4.4.1
16	Inter Laboratory Comparisons (PT/ EQAS)	5.6.3.1
17	Storage, retention and disposal of clinical samples	5.7.2
18	Release of results	5.9.1



However, a single document may address the requirements for one or more procedures. For example, Responsibilities, Authority and Interrelations (4.1) may be combined with Personnell (5.1) and may be stated in the quality manual in the form of an organogram. Documentation (4.3) and Control of Records (4.13) can be combined. Equipment management including Selection, purchase and management of equipment, Calibration of Equipment, Preventive Maintenance of Equipment can be combined. Pre-examination activities including, Establishment of service agreements, Collection, and Handling of samples, Storage, Retention and disposal of clinical samples can be combined

Alternatively, the requirement for a procedure may be covered by more than one document.

The major elements to be addressed while writing a QSP are the Purpose, Scope, Responsibility, and Method.

A sample QSP document referring to 4.3 Document Control Annexure 8

3.6.2 Standard Operating Procedure (SOP)

Procedures are the specific activities of a process; a procedure is easily described as the performance of a test. A procedure explains “how to do it.” SOPs are required for all testing done in the lab procedures

a) Attributes of a Standard Operating Procedure (SOP)

Standard Operating Procedures (SOP) contain written step-by-step instructions that laboratory staff should meticulously follow when performing a procedure. A laboratory will have many SOPs, one for each procedure conducted in the laboratory.

Written SOPs ensure the following.

Consistency - Everyone should perform the tests exactly the same so that the same result can be expected from all staff. Consistency enables people who use laboratory results to observe changes in a particular patient’s results over time; if different laboratories use the same SOPs, comparisons of their results can be made; it should be emphasized that all laboratory staff must follow the SOPs exactly.

Accuracy - Following written procedures help laboratory staff produce more accurate results than relying on memory alone because they won’t forget steps in the process.

Quality - Together, consistent (reliable) and accurate results are primary goals of the laboratory, and could be considered as the definition of quality in the laboratory.

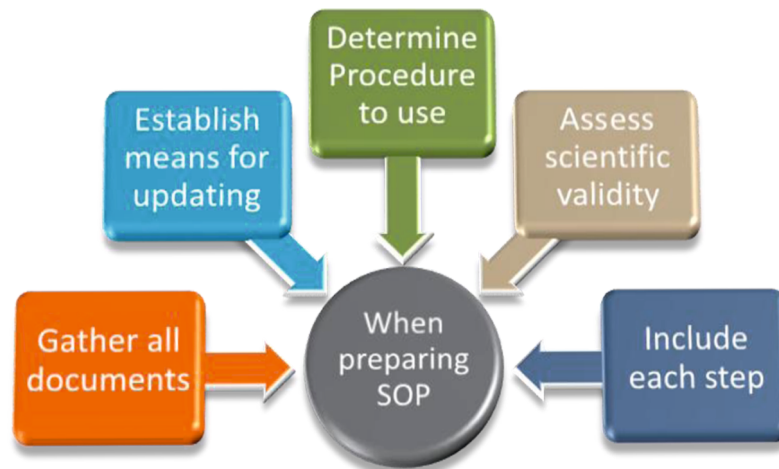
A good SOP should be **detailed, clear, and concise** so that staff not normally performing the procedure will be able to do so by following the SOP. All necessary details, for example, ambient temperature requirements and precise timing instructions, should be included.

A good SOP should be **easily understood** by all including, new personnel or students in training.

An SOP should be written in local language clearly understand by users and should be displayed / placed at an easily accessible location.



b) Preparing an SOP



There are a few things to keep in mind when preparing an SOP. Firstly, it is important to assess the scientific validity of the procedure. Then, when writing the procedure, include all steps and details explaining how to properly perform the procedure. The SOP should refer to any relevant procedures that may be written separately, such as instructions for sample collection or quality control. Finally, a mechanism should be established for keeping SOPs updated.

As per ISO: 15189, 5.5.3 (**Documentation of examination procedure**), 20 elements are to be addressed within an SOP (sub-clauses a-t), as follows:

- a. Purpose of examination
- b. Principle and method of the procedure for examination
- c. Performance characteristics
- d. Type of sample
- e. Patient preparation
- f. Type of container and additive
- g. Required equipment and reagent
- h. Environment and safety controls
- i. Calibration
- j. Procedural steps
- k. Quality Control Process
- l. Interferences (Lipemia, Icterus, Hemolysis, Drugs) and cross-reactions
- m. Principle and procedure where relevant measurement uncertainty of measured quantity
- n. Biological reference intervals or clinical decision values
- o. Reportable interval of examination
- p. Instructions for determining quantitative results, when result is not within measurement interval
- q. Alert/ critical value



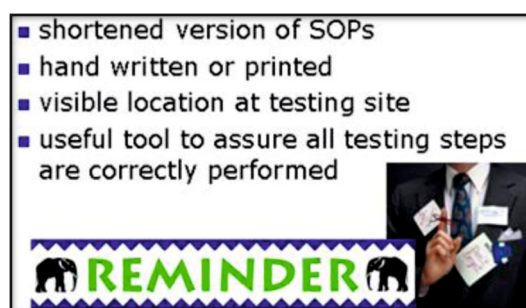
- r. Clinical Interpretation
- s. Potential sources of variation
- t. References

Manufacturer's Instructions: The instructions that manufacturers provide in their product explain how to perform the test, but do not include other important information that is specific to laboratory policy, such as how to record results, algorithms outlining the sequence of testing, and safety practices. The manufacturer's instructions may describe recommended quality control procedures for the test, but the recommendations may not be as comprehensive as protocols that a laboratory has put into place. Do not rely solely on manufacturer product inserts for SOPs. Use information from these inserts, but develop SOPs specific to your laboratory.

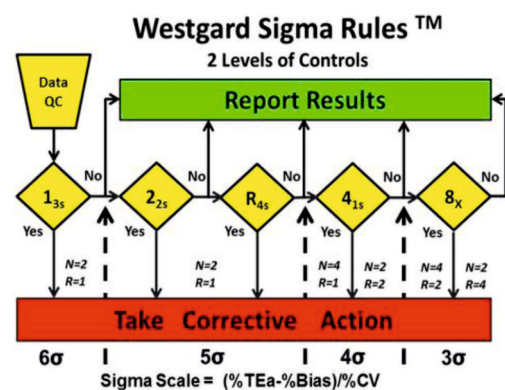
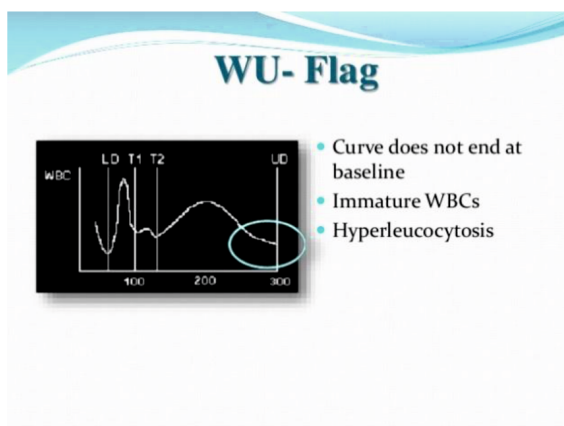
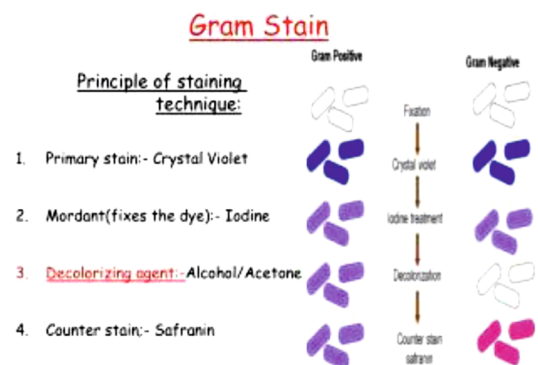
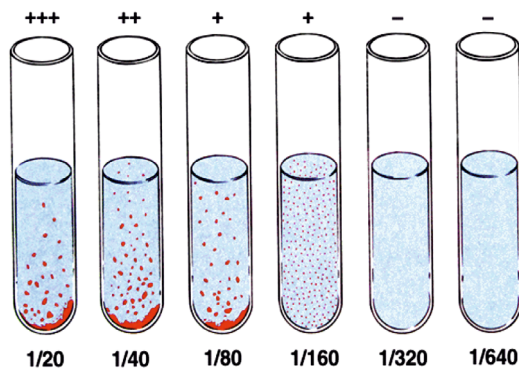
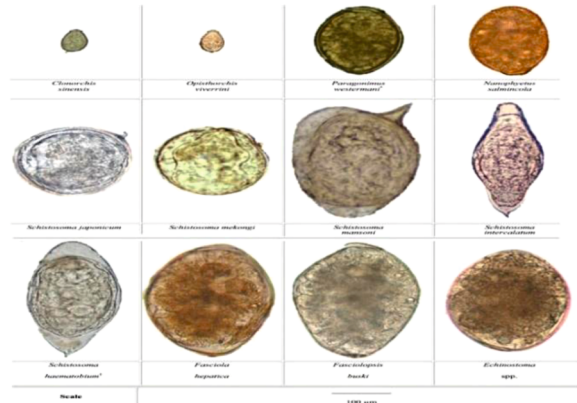
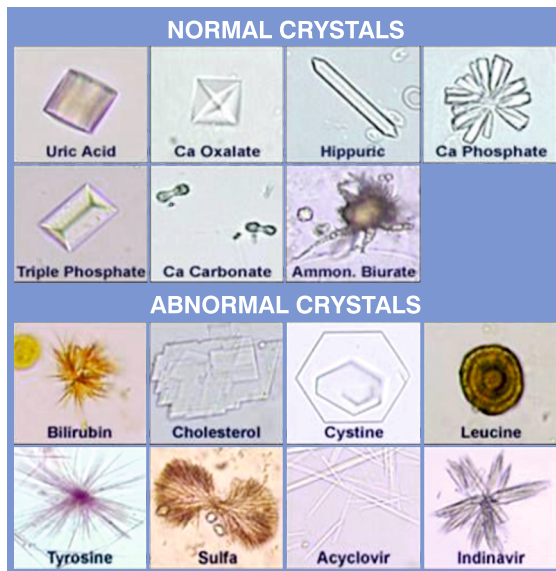
Sample SOP: Annexure 9

3.6.3 Job Aids/ Bench Aid/ Work Desk Instructions/ Work Instructions, are shortened versions of SOPs that can be posted at the bench for easy reference on performing a procedure. They are meant to supplement, not replace, the SOPs. It should be placed in a visible location, and serves as a reminder of the steps that need to be completed. The Job Aid and the SOP must include the same instructions, though all the

information in the SOP will not be available in the Job Aid. If a Job Aid is distributed to sources outside the laboratory, ensure that the information illustrated matches that which is instructed in the SOP. External laboratory assessors often check to see if Job Aids are in accordance with SOPs. All Job-Aids are required to be under document control.



Some examples of Job-Aids



DESIGNING FORMATS, KEEPING RECORDS

3.7 Formats and Records

- A form is a place to record data.
- A form with data is now a record.
- A record provides objective evidence of data, activities, etc. and it helps to establish evidence of conformance to QMS requirements.
- Organizations must retain records that are legible, readily identifiable and retrievable.

3.7.1 Identifying the list of formats required in a lab

The lab should identify the activities that need formatting. These activities are those which need documentary evidence. A few examples will be preventive maintenance schedule of machines, breakdown and downtime information and so on. A good way to understand the format requirement is to consider all activities as per ISO 15189 standard and list out second and third level documents simultaneously. The table below shows a clause-wise listing of secondary and tertiary level documents for a few management and technical clauses. The lab may decide how it may define the need for its records. The following format may also be used for the master log development.



Format 1: Sample Master log 1 (As per ISO Clauses)

Clause No.	Second Level Documents		Third level Documents		Other Records
	Document Number	QSP / SOP / External Document	Form / Record Number	Form Title	
4.1			R: 01		Legal identity
4.3	QSP 1	Document control	F: 01	Document Approval Issue and Revision Control	
			F:02	Control of External Origin Documents	
			F: 03	Document Amendment Note	
4.4	QSP 2	Establishment and review of Service agreement	F: 05	Formats for review of contract	Bills Photocopies of reports of tests outsourced
4.5	QSP 3	Selecting and evaluating referral labs	F:06	Format with selection criteria	MoU
			F: 07	Formats for periodic evaluation of referral labs	Photocopies of reports of tests outsourced
4.6					
4.7					
...					
...					
...					
5.5	1. SOP:1 2. SOP:2 3. SOP:3 4. SOP:4	Biochemistry/ hemat/ micro/ histo/ cyto or SOP a machine List of bench-aids	F: ...	Report recording in the case of manual assays	Printouts
			F..	Method validation for in-house validated tests	
			F...	Verification of new tests	
			F:...	Retesting formats	
			F...	Formats for change of biological reference change	
	External Documents				
	ED1: Operating Manuals				
	ED2: Validation papers				
	T 1: Text Book				
	T 2: Text Book				
	ED: 3 Kit inserts				
5.6					

QSP: Quality System Procedures, SOP: Standard Operating Procedure, ED: External Document, T for Text Book, F: Format, R: Record (See Developing a Document Control System for the suggested numbering system)



3.7.2 Designing formats:

Several activities in a lab need formatting to be captured as records. While designing a format, ensure that all required information for the purpose for which it is designed, is are met. Overcomplicating a format or multiple formats for a function will lead to improper recording of information

All formats should come under document control and show the traceability to a second level document that refers to the activity. Should a format require reformatting to capture additional information than originally envisaged, it should indicate the revision number and date of issue. The reason for revision must be noted, all obsolete formats must be removed from circulation to prevent inadvertent use. One obsolete stamped format should be saved for future reference. A file of all in-use ('controlled' stamped) and obsolete ('obsolete' stamped) formats should be available in the lab.

An example of a breakdown and downtime monitoring format is shown below. Such a format should essentially have the identification details of the machine, time and details of the breakdown, if it is a recurrent problem, downtime and details of the tech support personnel. Additional information like Turn Around Time (TAT) violations may also be captured in the format.

Format 2: Equipment Downtime Monitoring Format

Machine Downtime Monitoring

Format Number..... Level 2 reference.....
Date of issue/ reissue..... Revision number.....
Name of machine..... Department..... Machine ID.....

SI No.	Breakdown Date and Time	Details of breakdown	Has the problem happened earlier?	Repair complete date and time	Attended by	Downtime

RECORDS!



Once a format gets filled with data elicited in the lab, it becomes a record. A record cannot be amended.

3.7.3 List of records mandated by ISO 15189:2012

Many kinds of records are produced in a laboratory. Some examples include:

Sample log book, registers, laboratory workbooks/sheets, instrument printouts, maintenance records, quality control data, EQA / PT records, patient test reports, personnel records, results of internal and external audits, continuous improvement projects, incident



reports, user surveys and customer feedback, critical communications: i.e. letters from regulatory agencies, from government, or maybe from administrative offices within the healthcare system, information on the management and handling of rejected samples, data needed on any sample referred to another laboratory (to include when the sample was transported, where it was sent, and when the report was issued; the sample should be able to be tracked throughout the referral process), information about adverse occurrences or problems (Include all information that is pertinent, such as the results of any investigation of the problem), inventory and storage records, equipment records.

Some of the records from lab activities are captured on lab designed formats. Some lab activities generate printouts. Some records like EQAS reports are generated outside the lab. Regardless of the nature of the record, a systematic approach should be taken towards classifying and filing them so as to enable ready retrieval.

Remember to keep these!! Understand the retention times of each

**Figure 5: Record of Permission for Bio-Medical Waste Generation.
Retention Period: Till next Renewal(or as defined by the lab)**

**मध्य प्रदेश शासन
आवास एवं पर्यावरण विभाग,
गन्नासरा, भोपाल**

-आधिर्यचना-

भोपाल, दिनांक /2006

कमांक एफ-7-92/97/मलीन जीव चिकित्सा अपशिष्ट (प्रबंधन एवं हस्तगत) नियम 1998 के नियम 8(3) द्वारा प्रवृत्त शक्तियों को प्रयोग में करते हुए राज्य सरकार प्राधिकार/प्राधिकार नवीनीकरण फीस में सरल शर्तों के उपरान्त निम्न पैरा प्रविष्ट करती है :-

<u>प्राधिकार/प्राधिकार नवीनीकरण फीस</u>	
1. मलीन जीव, वैद्यकीय, प्रयोगशालाएं और रक्त कोष	रुपये 1000/-प्रतिवर्ष
2. पशु संस्थान/औषधालय	रुपये 1000/-प्रतिवर्ष
3. स्टाफ हाउस	रुपये 5000/-प्रतिवर्ष
4. अस्पताल हेल्थ कोरर संस्थाएं/नर्सिंग होम	चार बीघा तक रुपये 1000/-प्रतिवर्ष इसके पश्चात् रुपये 100/प्रति बीघा/प्रतिवर्ष की दर से अतिरिक्त
5. जीव चिकित्सा अपशिष्ट की परिवहन सुविधा	रुपये 7500/प्रतिवर्ष
6. जीव चिकित्सा अपशिष्ट की प्रसंस्करण सुविधा	रुपये 10,000/-प्रतिवर्ष

"जीव चिकित्सा संस्थानों जीव चिकित्सा अपशिष्ट की प्रसंस्करण सुविधा को आवेदकों द्वारा अपना प्रोजेक्ट स्वीकृत न किया जाकर अन्यत्र स्थापना का प्रस्ताव प्रस्तुत किया जाता है अथवा एक बार स्वीकृत करी के कुछ समय के बाद प्राधिकार/नवीनीकरण प्राप्त कर प्रोजेक्ट को बंद कर दिया जाता है एवं शुल्क का वापसी नहीं जाती है अथवा प्रस्तुत शुल्क किसी अन्य माद अथवा किसी अन्य अलग स्थान पर स्थापित प्रोजेक्ट हेतु समायोजित करने का आवेदन देने की स्थिति में जीव चिकित्सा अपशिष्ट (प्रबंधन एवं हस्तगत) नियम 1998 के अंतर्गत प्राधिकार/ प्राधिकार का नवीनीकरण कराने हेतु प्रस्तुत शुल्क की 15 प्रतिशत राशि बोर्ड द्वारा प्रतिष्ठागत व्यय के दिवस फाटी जाकर, आवेदक के लिखित अनुरोध पर शेष राशि आवेदक को लौटाई या सक्ती अथवा उसको लिखित आवेदन पर किसी अन्य परियोजना हेतु समायोजित की जायेगी । यह प्रावधान उन प्रकरणों पर ही लागू होगा जहाँ परियोजना की स्थापना एवं संचालन, प्राधिकार/ नवीनीकरण हेतु शिवालयीन अर्थात् में प्रारंभ नहीं किया गया हो । प्राधिकार/ नवीनीकरण शुल्क वापसी संबंधी निर्णय प्रत्येक प्रकरण के अनुसार लिया जायेगा । "

मध्य प्रदेश के राज्यपाल के नाम से
तथा आदेशानुसार
हस्ता /
(जी.एन. त्रिपाठी)
उप सचिव
मध्य प्रदेश शासन
आवास एवं पर्यावरण विभाग

.शिरदार (7)

Figure 6 : EQAS report Biochemistry Retention Period
1 year(or as defined by the lab)

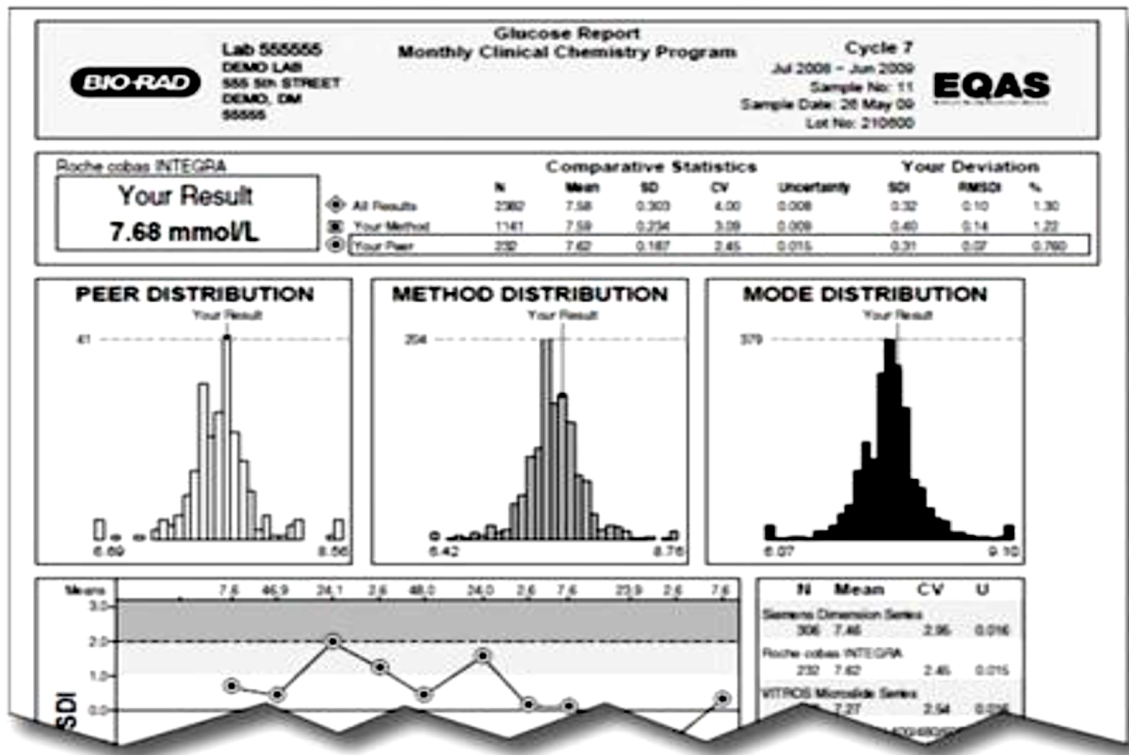
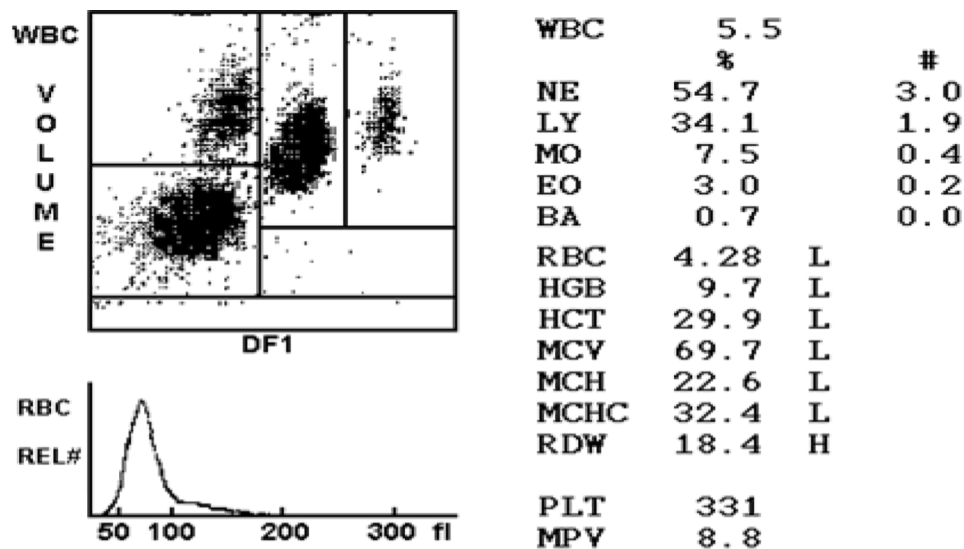


Figure 7: Machine Print Out– CBC, Retention Time 1 week (or as defined by the lab)



ISO: 15189 Clause 4.13 mandates records specified in subclauses a-v as the minimum record requirement of each lab

Records shall include, at least, the following:

- Supplier Selection and Performance, and Changes to the Approved Supplier List
- Staff Qualifications, Training, and Competency Records
- Request for Examination



- d. Records of Receipt of Samples in the Laboratory
- e. Information on Reagents and Materials Used for Examinations (e.g. Lot Documentation, Certificates of Supplies, Package Inserts)
- f. Laboratory Work Books or Work Sheets
- g. Instrument Printouts and Retained Data And Information
- h. Examination Results and Reports
- i. Instrument Maintenance Records, Including Internal And External Calibration Records
- j. Calibration Functions And Conversion Factors
- k. Quality Control Records
- l. Incident Records and Action Taken
- m. Accident Records and Action Taken
- n. Risk Management Records
- o. Nonconformities Identified and Immediate or Corrective Action Taken
- p. Preventive Action Taken
- q. Complaints and Action Taken
- r. Records of Internal and External Audits
- s. Inter-Laboratory Comparisons of Examination Results
- t. Records of Quality Improvement Activities
- u. Minutes of Meetings that Record Decisions made about the Laboratory's Quality Management Activities
- v. Records of Management Reviews.

All of these quality and technical records shall be available for laboratory management review (see 4.15).

A test report is also a record. The following is a list of test report contents required by ISO 15189 (5.8.3 a-p)

Identification of test, identification of laboratory, identification of the referral lab, unique identification and location of patient, where possible, and destination of the report, name and address of requester, date and time of collection, and time of receipt in laboratory, date and time of release of report, primary sample type, results reported in SI units or units traceable to SI units, where applicable, biological reference intervals, where applicable, interpretation of results, where appropriate, applicable comments relating to quality or adequacy of sample, methodology limitations, or other issues that affect interpretation, identification and signature of the person authorizing release of the report and if relevant, notation of original and corrected results

3.7.4 Inter-relationship of a Policy, Process, Procedure, Formats, Records

Please see the table below to understand how policy becomes a procedure through a process and leaves evidence on formats in the form of records. Let us see the documentation in establishment, implementation and maintenance of 4.3 Document Control



RECAP!!

Table 3.2: Inter-relationship of a policy, process, procedure, formats, records

Policy	Process	Procedure	Records
Statement of intent	Define activities that transform intent into action	Performing the activity	Evidence retained
“The lab will maintain a document management system as per standard guidelines.”	The lab writes a QSP for Document management to include all essential elements • <i>Process for identification of documents</i> • <i>Process for creation, review and approval of new documents</i> • <i>Process for changing documents</i> • <i>Process for periodic review of documents</i> • <i>Process for archival, storage and retention of documents</i>	The lab follows all the activities as said in the QSP and maintains all records • <i>Creating, identifying, revising, reviewing, and approving documents</i> • <i>Control of both internal and external documents</i> • <i>Changing approved documents</i> • <i>Archiving documents</i> • <i>Storing and retaining archived documents</i>	The lab records the activities and keeps records as evidence • <i>Document Approval and Revision Control</i> • <i>Control of External Origin Documents</i> • <i>Document Amendment Note</i> • <i>Permission for records destruction</i> • <i>List of archived documents</i>



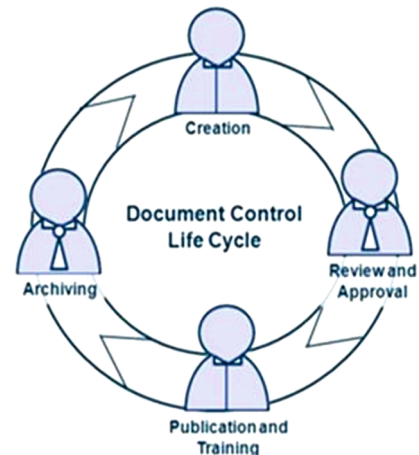
Chapter 4

Document Control: Maintaining the Inventory of Documents

4.1 Learning Objectives:

At the end of this chapter the learners should be able to describe

- The purpose of Document Control
- Examples of controlled documents
- The elements of document control system
- How to develop a document control system
- Implementation of a new document control system
- The need for data archival
- Common problems in relation to documentation



4.2 Purpose of Document Control

A document control system provides a method for formatting documents so that they are easily managed and sets up processes for maintaining the inventory of documents. Documents, by definition, require updating. A system must be established for managing them so that current versions are always available.

Document control assures the use of most current version



4.3 Examples of controlled documents

Documents that should be considered for document control are those which may vary based on changes in versions.

- ♦ Standard Operating Procedures (SOP)—it is essential to have all SOPs up-to-date, showing the procedures that are in current use. Also, when work instructions or job aids are used, they must exactly match the SOPs for the tasks described.
- ♦ Texts, articles, and books that are part of the documents referenced in a laboratory;
- ♦ Documents of external origin, such as instrument service manuals, regulations and standards, and new references (that may change over time).
- ♦ Other examples include, policy statements, instructions for use, flowcharts, procedures, specifications, forms, calibration tables, biological reference intervals, charts, posters etc. (ISO 15189:2012 Clause 4.3 - Note).

4.4 Elements of document control system

ISO mandates that:-

- a. All documents including those maintained in a computerized system issued as part of the QMS should be reviewed and approved by authorized personnel
- b. All documents should be identified to include
 1. A title
 2. Unique identifier on each page
 3. Date of current edition and edition number (Revision/Version)
 4. Page number to total number of pages
 5. Authority of issue
- c. Current authorized editions and their distribution are identified by a list (e.g. document register, log or master index)
- d. Only current authorized editions are available at the points of use
- e. Where a laboratory's document control system allows for the amendment of documents by hand, pending reissue of documents, the procedures and authorities for such amendments are defined, amendments are clearly marked, initialled and dated, and a revised document is issued within a specified time period



- f. Changes to document are identified
- g. Documents remain legible
- h. Documents are periodically reviewed and updated
- i. Obsolete documents are clearly marked
- j. At least once copy of an obsolete document is retained for a specified period

4.5 Developing a document control system

A document control system provides a method for formatting documents so that they are easily managed, and sets up processes for maintaining the inventory of documents. In this system the laboratory will need:

A **uniform format** should be developed that includes a numbering system and a method for identifying the version (date) of the document system for standardizing the format and/or numbering. It is very useful to have a numbering or coding system that applies to all documents created within the organization. Because documents are “living” and require updating, the numbering system should indicate the document version. One suggestion for a numbering system is to use a letter for the type of document, then an incremental number for each of the documents of this kind. All pages of the documents would contain the appropriate number. For example, R1, R2, R3 for non-formatted records, F1, F2.... for formats; T1, T2, for official texts, RG1 1, RG 2 registers, etc. Establishing a document numbering system can be a difficult and time-consuming process. If the laboratory already has an effective system in place, there is no need to change it. A location code could be used, and would be useful for the master log or file.

A good document should be **reviewed and approved** by the laboratory management. Approval is indicated by a signature and a date. It should be **updated on a regular basis, and the revision details noted in the documents**

4.5.1 Standardizing the format: Headers and footers will enable this process in as much that all staff can easily recognize the flow of information.

Headers are of 2 kinds:

Format 3a – Complete Standardized Headers

- I. A **complete standardized header** which would appear on the first page of all documents.

Name of Hospital/ Department	Document identity	Page 1 of....
Name of Manual		
Prepared by:	Issued by	
Issue Date:	Issue Number:	
Original date of issue:	Next Review date:	



Format 3b – Reduced Standardized Headers

II. **Reduced standardized header:** a smaller version that will appear on all pages

Name of Hospital/ Department	Document identity	Page 1 of....
Name of Manual		

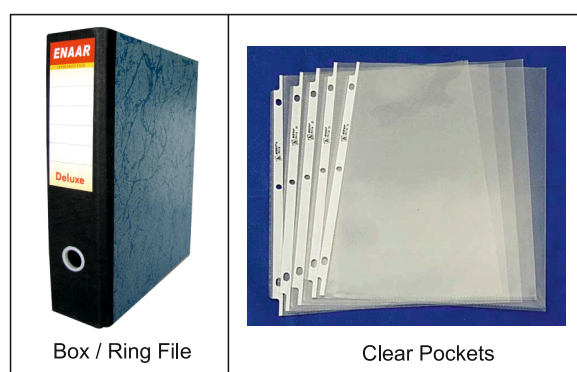
4.5.2 Process for formal approval, updating and revising laboratory documents and a **distribution plan** or list.

- ♦ Control of documents requires that they be reviewed on a regular basis, with revision as needed, followed by approval and distribution to those who need them.
- ♦ The review and approval process is generally performed by laboratory management, and approval is indicated by signatures with appropriate dates.
- ♦ Policies for the approval, distribution and revision of documents should be clearly established as a part of the Documents and Records policy.
- ♦ An in-use document should be “controlled” stamped.
- ♦ Every amendment should be documented in the amendment page. The lab can decide on how many amendments it will incorporate before the issue is changed and how it will convey the amendments to the readers before and after the issue change. The lab may also decide if the amendments will be made by hand, pending reissue

**CONTROLLED
DOCUMENT**

An example for an amendment without reissuing the entire document.

- Assume the SOP of biochemistry contains all tests done on a particular machine. Now assume that the Glucose method has changed from Oxidase Peroxidase to Hexokinase. You may obsolete the Oxidase Peroxidase SOP and in its place keep an approved, controlled, appropriately dated version of Hexokinase method. This amendment will be noted in the amendment page and signed by the approval authority. The changes will be informed and taught to the user. The user’s signature also may be taken to ensure that the information has been disseminated and received.
- Now assume that several method changes have happened, and far too many amendments have been made. At this point, you may reissue the document. However, at every reissue, all the amendments made should be noted down on the amendment page



The box file with ring binder and clear pockets used for documents will enable minor amendments without disturbing the entire volume. This is just a suggestion, the lab may decide on the medium of the document; soft or hard and the finer details



Format 4 : Document Amendment Format

Sl No.	Page number	Section/ page amended / revised	Nature of amendment / revision	Date of amendment / revision	Signature of person authorizing revision / amendment

4.5.3 Assuring Accessibility: a process to ensure that the documents are available to all who need them, including users outside the laboratory. The document control plan must provide a process for assuring that relevant versions of documents are available at the point of use. This may include provision for having current sample collection information available outside the laboratory if collection is performed in other places such as hospital wards or physician offices.

Format 5 : Distribution List Format: With example

Name and Identity of Document	Controlled copy No.	Name/ Designation of the holder of controlled copy	Signature of authority
Sample Collection Manual	03	Ward 10 Sister in charge	

4.5.4 Preventing use of obsolete documents:

Assure that the most **current version** of any document is the one that is in use. **Unintended use of obsolete** documents is prevented. A system should be evolved to ensure that all the obsolete versions are removed from the point of use, and only current authorized versions are used

4.5.5 Archival of Documents

A method for archiving documents that become outdated but need to be kept for future reference should be in place. Remember that archiving old versions of documents will be very important. It is frequently should be in place necessary to refer to older versions of documents when researching a problem, or when reviewing quality practices. As a part of the distribution process, it will be necessary to collect all old versions of the documents for archiving/destruction.



Importance of storing Documents and records

The long-term storage and retrieval of laboratory data is necessary for reviewing results, addressing complaints and for research reasons

Manual Archival

It is important to consider the following when using a paper system for records:

- **Permanence** - paper records must last for as long as needed. This should be ensured by binding pages together, or using a bound book (log register). Pages should be numbered for easy access, and permanent ink used.
- **Accessibility** - paper systems should be designed so that information can be easily retrieved whenever needed.
- **Security** - documents and records must be kept in a secure place. Security considerations include maintaining patient confidentiality. Care should be taken to keep documents safe from any environmental hazards such as spills. Consider how records can be protected in the event of fires, floods, or other possibilities.
- **Traceability** - it should be possible to trace a sample throughout all processes in the laboratory, and later to be able to see who collected the sample, who ran the test, and what the quality control results were for the test run including issuing of the report.
- This is important in the event there are questions or problems about any reported laboratory result. All records should be signed, dated, and reviewed to ensure that this traceability throughout the laboratory has been maintained.

Electronic data archival

- Ensure permanence by system maintenance and backup
- Ensure security through access control, audit trails, and confidentiality
- Ensure traceability through good data

Retention time for various records

The laboratory shall decide the retention time of records as per the national, regional and local regulations. However, NABL requires following minimum retention time for ensuring the quality service and patient care:

- Particle Cell counter data – one week
- Molecular diagnostic gel pictures – 5 years
- Flow cytometry/ Immunophenotyping data – 6 months (values only)
- Electrophoretogram – 1 year
- Haemoglobin HPLC data – 1 year
- Coagulation calibration/ standard graph – 1 week
- Table/ chart of daily values for internal quality control – 1 year

The minimum period for retention of test reports issued shall be five years for Histopathology and Cytopathology and one year for other disciplines.



- 4.5.6 Creating Master Log** - this will allow the person responsible for document control to know exactly what is in circulation, and where copies can be found. The log should be kept up-to-date at all times. A sample master log format is given below

Format 6: Sample Master Log 2 (As per Lab Document Identity)

Document Number	Document Name	Issue / Version Number	Issue / Version Date	Revision/ Amendment Num	Revision / Amendment Date	Copy Holder	Location	Approval Authority
D 01	Quality Manual	01	1/11/15	00	00	Quality Manager	QM office	Medical Supt
D 02	QSP	01	1/12/15	00	00	Quality Manager	QM office	HOD

**Version number and issue number are synonymous.
Similarly revision number and amendment number are synonymous.**

- 4.5.7 Developing an Audit Trail System:** While developing an electronic documentation system it is very important to enable an audit trail system. **Audit trail** is a record showing who has accessed a computer system and what operations s/he has performed during a particular period. It is useful for maintaining integrity of data, system security and encouragement of personal accountability

4.6 Implementing a new document control system

When implementing a new document control system, the following steps will be needed:

- 1. Collect, review, and update** all existing documents and records. Usually, a laboratory without a document control system will find many outdated documents that will need to be revised.
- 2. Determine additional needs;** once all documents have been collected, it should be possible to determine needs for new process or procedure descriptions. If the quality manual has not yet been developed, this should probably be done at that time as it serves as the framework for all the efforts.
- 3. Develop or obtain examples of documents,** including forms and worksheets, if needed. Remember that forms of all kinds are documents, but once they have information added, they become records. Assess all activities that need formatting to obtain records. In order to help with formatting, examples from other laboratories or published materials can be used.
- 4. Involve stakeholders:** It is useful when creating documents to be used in the laboratory to involve all staff who will be using them. For documents that will be used outside the laboratory, such as reports, it is very helpful to seek input from those who will use the reports



4.7 Common problems

Some of the common problems found in laboratories that do not have document control systems or that do not manage their document control systems include the following:

- a) Out-dated documents in circulation.
- b) Distribution problems: If multiple copies of documents are dispersed throughout different areas of the laboratory, it will be cumbersome to gather all copies when it is time to update them, and some could be overlooked. Out-dated copies end up in use. For this reason, multiple copies should be avoided. Documents should not be distributed more widely than needed, and a record should be kept of where all documents are located. While retrieving old documents, it should be checked against the master log to ensure that all copies are withdrawn.
- c) Failure to account for documents of external origin: These documents may be forgotten in the management process, but it is important to remember that they may also become out-dated and need to be updated.
- d) Not logging kit inserts: The instruction may change over time and may go unnoticed especially while using the same brand.
- e) Forms are inadequately designed to meet laboratory and client needs
- f) Standardized forms prepared by others may not be suitable for all laboratories
- g) Inability to retrieve data due to poor archiving processes or insufficient back-up of computerized information



If you can answer these questions satisfactorily, that means your document control is working

How do you approve documents for release? – Who approves them? How will you know a document has been approved?

How do you review, update and re-approve documents? – Do you review on a regular basis? Who does the review? Who is responsible for making changes? How is an updated version approved?

How do you identify the changes that have been made and how do you identify the revision status? – How will you know what has changed between this version and the latest release? How do you know what version your copy is, or the version of this paper copy you found?

How do you provide access to the correct version where it's needed? E.g. in the ward- Are there hard copies to update? How do you keep track of them? Who is responsible for distributing or updating to the latest version?

How do you find and control documents from external sources? E.g. relevant standard, supplier product specifications. “Control being all the previous questions on approval, review, updates, access....”



Bibliography

1. CLSI. Quality Management System: a model for laboratory services; approved guideline. 4 ed. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.
2. ISO. ISO:15189:2012 Medical laboratories - particular requirements for quality and competence. ISO, Geneva; 2012. 3 ed. Geneva: International Organization for Standardization; 2012.
3. ISO. ISO:9001:2008 Quality Management Systems - Requirements. Geneva: International Organization for Standardization, 2008.
4. WHO. Laboratory Quality Management System - Training toolkit. Geneva: Centers for Disease Control and Prevention; the World Health Organization; the Clinical and Laboratory Standards Institute, 2009.
5. NABL 112. Specific Criteria for Accreditation of Medical Laboratories. New Delhi: National Accreditation Board for Testing and Calibration Laboratories 2008 Issue date 01/2/2008, Amendment No.03; Amendment date 16/10/2012)
6. NABL 160. Guide for Preparing a Quality Manual. New Delhi: National Accreditation Board for Testing and Calibration Laboratories, 2012.

Annexures

Annexure 1	Sample Quality Policy	40
Annexure 2	Sample Quality Objectives	41
Annexure 3	NABL-160 (13-17)	42
Annexure 4	Example of Quality manual, addressing a clause 4.3 of ISO 15189	47
Annexure 5	Process Flow Chart Clause 4.3	49
Annexure 6	Example of a Process Table/Matrix Clause 5.2	50
Annexure 7	Example of a Process Flow Chart Clause 5.3	51
Annexure 8	Example of a Quality System Procedure Clause 4.3	52
Annexure 9	Example of a SOP	55

Annexure 1

Writing Quality Policy

Quality Policy

XYZ Lab is committed to:

- a) Providing reliable, accurate & easily accessible laboratory services to all its users in the fields of **Clinical Biochemistry, Clinical Pathology, Haematology, Cytopathology, Histopathology, and Microbiology & Serology.**
- b) Performing lab tests by means of utmost competent & professional practices conforming to national/international standards.
- c) Planning, establishing & periodically reviewing quality objectives to meet the requirement of the users, in line with the ISO 15189:2012 & for the continual improvement in the quality of lab's services.
- d) Ensuring that the entire Lab team is fully familiarized with the Quality Management System, ultimately focusing on the end user's satisfaction.
- e) Ensuring that this policy will be reviewed periodically to make necessary changes

Annexure 2

Writing Quality Objectives

Clauses addressed: 5.3 and 5.4

STORES / PURCHASE 5.3

- ♦ Ensure zero TAT violation on account of Inventory disruption

EQUIPMENT 5.3

- ♦ Optimize equipment performance and reduce downtime
- ♦ Minimize TAT violation due to breakdowns <1%
- ♦ Backup machines in all departments

SAMPLE COLLECTION 5.4

- ♦ To reduce the patient waiting time at the counter to less than 15 minutes.
- ♦ To ensure that the number of nonconforming specimens taken by the phlebotomist should not exceed 1 %.
- ♦ To maintain records especially with reference to time of collection and identification of phlebotomists.

Annexure 3

NABL-160 (13-17)

TITLE PAGE

The title page of the Quality Manual should normally contain the following:

QUALITY MANUAL

of

(Name & Address of Laboratory)

Issue No. :

Issue Date :

Copy No. :

Holder's Name :

QUALITY MANUAL RELEASE AUTHORISATION

Immediately after the title page, this page should be placed. A typical authorisation should normally contain the following:

RELEASE AUTHORISATION

This Quality Manual is released under the authority of (name and designation of the Head of the laboratory) and is the property of

(name of the laboratory with address).

(Signature, Name & Designation)

Name of Laboratory:

Document No.:	Document Name: Quality Manual			
Issue No.:	Issue Date:	Copy No.:	Section No.	Page No.:
Amend No.:	Amend Date	Prepared by:	Approved by:	Issued by:



AMENDMENT PAGE

An amendment page should be inserted immediately after the title page. Specific instructions to each holder of the Quality Manual as to the amendment procedure to be followed to maintain each copy up to date should be included. To ensure that each copy of the Quality Manual contains a complete record of amendments, this amendment page should be updated and issued with each set of amended/ new pages of the Quality Manual.

A typical amendment page should normally contain the following:

AMENDMENT RECORD						
Sl	Page No.	Section/ Clause/ Para/ line (as applicable)	Date of Amendment	Amendment made	Reasons of Amendment	Signature of person authorizing Amendment
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

Name of Laboratory:

Document No.:		Document Name: Quality Manual		
Issue No.:	Issue Date:	Copy No.:	Section No.	Page No.:
Amend No.:	Amend Date	Prepared by:	Approved by:	Issued by:



CONTENT PAGE

For the ease of reference, the manual should contain a table of contents listing the major sections, sub-sections and their page numbers. A list of the Annexures should also be included.

A typical table of contents should normally contain the following:

CONTENTS				
Section	Contents			Page
	Quality Manual release authorization			
	Amendment sheet			
	Contents			
	Scope			
	References (if any)			
	Definitions (if any)			
	Abbreviations (if any)			
	Distribution List			
	Introduction (Brief description of the Laboratory & management system)			
	Quality Policy and Objectives			
	Management Requirements (4.1-4.15)			
	Technical Requirements (5.1-5.10)			
	List of all documents maintained by the laboratory			
	List of all records			
	List of all forms			
	Annexures (if any)			

Name of Laboratory:

Document No.:	Document Name: Quality Manual			
Issue No.:	Issue Date:	Copy No.:	Section No.	Page No.:
Amend No.:	Amend Date	Prepared by:	Approved by:	Issued by:

DISTRIBUTION LIST

The distribution record should list the holders of the controlled copies of Quality Manual with their allotted copy numbers. Copies of Quality Manual distributed as uncontrolled copies, should not be listed.

A typical distribution list should normally contain the following:

DISTRIBUTION LIST

The following are the authorised holders of the controlled copy of Quality Manual.

Controlled copy No.	Name/ Designation of the holder of controlled copy

Name of Laboratory:

Document No.:	Document Name: Quality Manual			
Issue No.:	Issue Date:	Copy No.:	Section No.	Page No.:
Amend No.:	Amend Date	Prepared by:	Approved by:	Issued by:



Annexure 4

Example of Quality manual, addressing a clause 4.3 of ISO 15189

DOCUMENT CONTROL

The laboratory controls documents required by the quality management system and ensures that unintended use of any obsolete document is prevented. All hard copy documents are “controlled” stamped. Soft documents are password protected. Soft copies of all documents (Word and Excel files) are retained by the person(s) who has/have drafted them. Any changes therein shall only be amended by the person(s) who has/have drafted them. The document is then cross checked with the previous version of document’s hard copy. Previous soft documents are immediately deleted and hard copy documents are stamped as obsolete and a copy retained. The electronic signatures are also not retained in any of the soft copies after the final document’s hard copy is generated.

The laboratory has documented procedure to ensure that the following conditions are met

- a. All documents including those maintained in a computerized system issued as part of the quality management system are reviewed and approved by authorized personnel before issue.
- b. All documents are identified to include a title, a unique identifier on each page, the date of the current edition and / or edition number, page number to total number of pages (e.g. page 1 of 5, page 2 of 5), authority for issue
- c. Current authorized issues and their distribution are identified by means of a list: (M57 : Master Log)
- d. Only current authorized issues of applicable documents are available at points of use
- e. The laboratory’s document control system allows for the amendment of documents by hand, pending the re-issue of document. The procedures and authorities for such amendments are defined, amendments are clearly marked, initialled and dated and a revised document is issued within a specified time period

- f. Changes to documents are identified. Amendment number with date, revision number with date, signatures of persons preparing and issuing are documented in the footer. All obsolete documents are appropriately stamped and removed from the work place and filed. The reason for amendment is noted where appropriate. The out-of-use excel files are stored in back-up discs
- g. Documents remain legible.
- h. Documents are periodically reviewed and updated at a frequency that they remain fit for purpose First 3 levels of documents reviewed once of year. All the amendments are listed in the amendment page. If more than twenty significant amendments are made, the issues are changed. Level 4 forms and formats are reviewed and amended as when required.
- i. Obsolete documents are dated and marked as 'obsolete'
- j. At least one copy of an obsolete controlled documents is retained for a specified time period or in accordance with applicable specified requirements

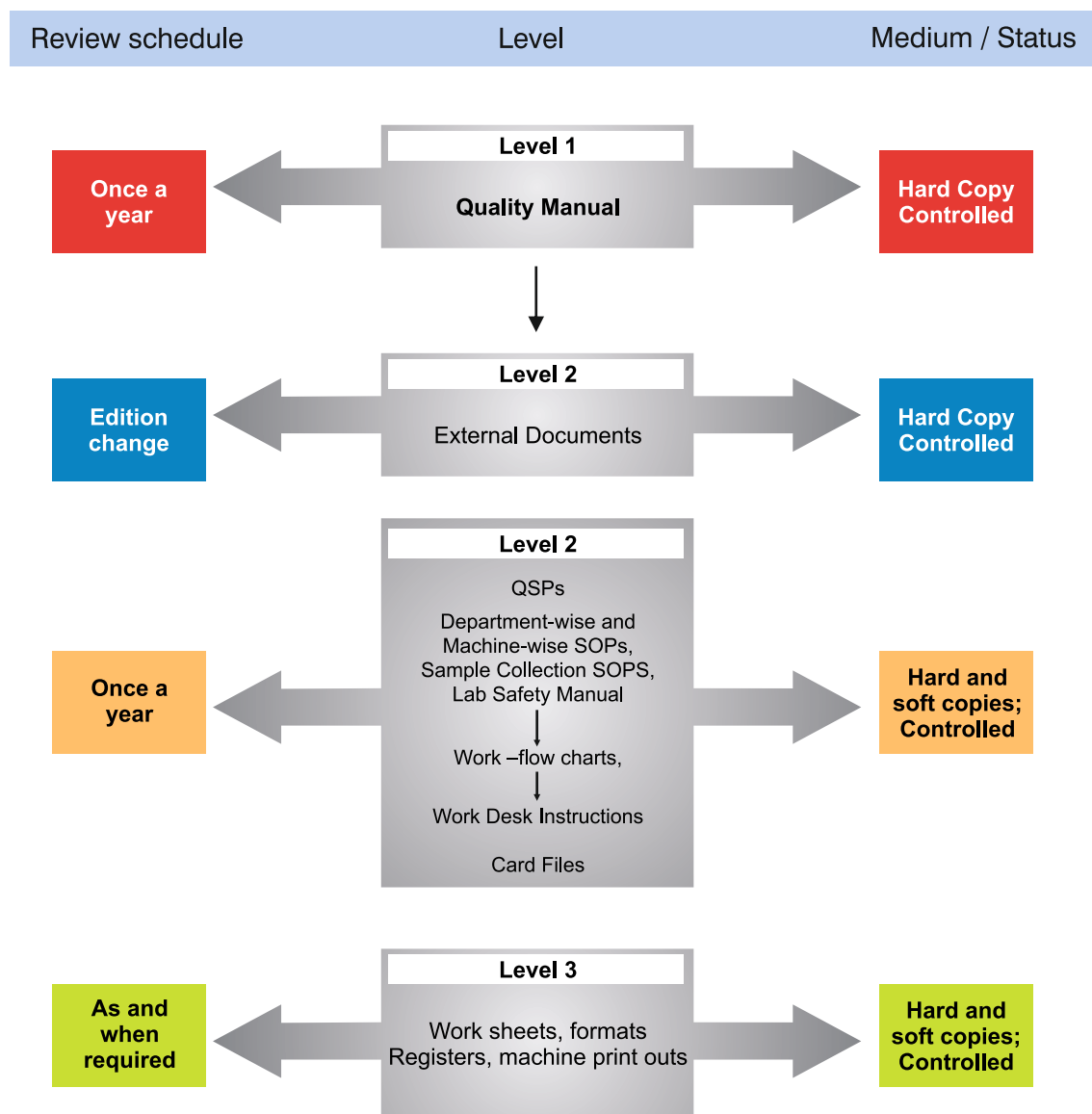
Reference: M: 05 QUALITY SYSTEM PROCEDURES Proceure 3, Annexure 5: Process Flow Chart, M: 57 Master Log



Annexure 5

Example of a Process Flow Chart Depicting the Process of Document Control, Review

PROCESS FLOW: DOCUMENTS



Annexure 6

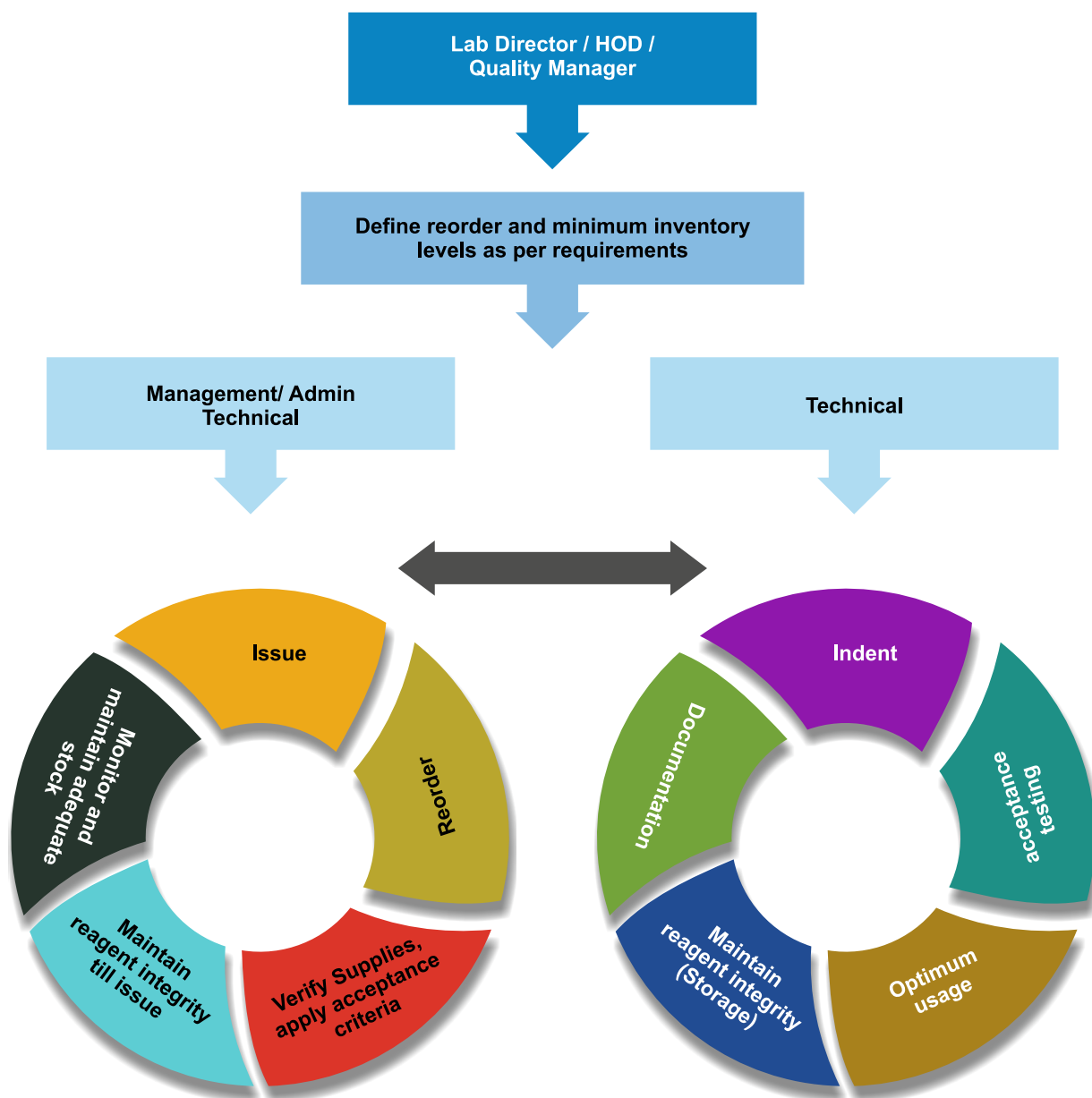
Example of a Process Table/Matrix

PROCESS INPUT / OUTPUT MATRIX: Lab Safety (5.2)				
Inputs	Process / Responsibility	Output	Records / Documents Maintained	Quality Objectives
Risks Bio Medical Wastes Bio Hazards in collection and processing Electrical hazards Equipment hazards Chemical hazards Glassware hazards Fire Hazards Safety Lab safety Manual Equipment handling guidelines Training Assurance of safe premises Hepatitis B vaccination MSDS sheets Fire Extinguishers, Fire blankets Fire Training PPE (Personal Protective Equipment) Eye wash Signage	Reading and understanding safety protocols Segregation at source as per guidelines. Pre-treatment before outsourcing BMW Observing standard precautions Abiding with the spillage and all safety polices Safe storage of chemicals Safe handling of equipment Participating in fire safety trainings and drills	Safe laboratory practices Elimination of occupational hazards	Risk Audit records NCE / Incident/Accident (Accidents, spills, lab acquired infections) CAPA records BMW records Training Records	Zero incidents/accidents Zero non-conformance Non - conformity

Annexure 7

Example of a Process Flow Chart

PROCESS FLOW CHART: INVENTORY CONTROL REAGENTS (5.3)



Annexure 8

Example of a QSP

CONTROL OF DOCUMENTS Clause 4.3 of ISO 15189

PURPOSE:

To ensure that the documents and data necessary to implement the quality system are identified and controlled so that only pertinent and updated documents are available and used by various personnel.

SCOPE: This procedure is applicable to the following documents

List of documents

- Quality manual
- Quality System Processes
- Standard operating procedures (SOPs) Department-wise / Machine-wise / Activity wise
- Formats and worksheets
- Master lists
- Kit Inserts
- Soft copies (Word and Excel) (Dept. wise)

RESPONSIBILITY:

- Policy documents are prepared by the Lab Director and QM in consultation with the higher management
- Quality System Processes are prepared by the Lab Director and QM in consultation with the Technical Managers
- SOPs of specific departments are developed by the HOD/ TM
- Work Desk Instructions (WDI) and formats are developed by Quality Manager by identifying and formatting the activities that require monitoring. Quality Manager is responsible for capturing the data on all formats and analysing and archiving it. Approval of all level 3 and 4 documents are to be done by the HODs

METHOD:

Types of Documents:

Level 1

Quality Manual:

This document describes the policies and intentions of the laboratories towards the quality systems as laid down in the ISO15189: 2012 and NABL 112. Uncontrolled soft/hard copies of the manual are sent to the external assessors. Controlled document, is with Quality Manager, to be made available for all staff.

Level 2

Quality System Procedures: This manual describes the activities which are carried out to achieve the policies laid down in the Quality Manual. Controlled document, is with the Quality Manager, to be made available for all staff.

SOPs: Dept. and machine-wise SOPs, Sample Collection Manual / Main lab, SOP for Collection Centres, Information for patients and users including Directory of Services and Lab Safety Manual. Controlled copies, located at the points of use

Work flow charts, Work Desk instructions, card files and kit inserts. All hard copies and soft copies of flow charts and WDI card files are approved, controlled and located at the points of use. Kit inserts are stamped controlled/ obsolete as per status and filed for a year

Level 3

Formats, Worksheets, registers and machine print outs: All hard copies & soft copies of formats are approved. Records are retained as per NABL112. Machine print outs are retained for a month.

Master List: It is the list of all files, controlled and uncontrolled, which describes the File no, location, date of issue, name of document, person in charge, status, issue date, approval authority and revision number. This involves QMS (Coded), Biochemistry AU-480 (coded - BIOCH), Haematology (coded - HMT)

Document Identity

Document identity includes a title, date of the current issue and issue number, page number to total number of pages, authority for issue.

Document Change/ Issue:

- Whenever a change in any document (soft or hard copies), (level 3-4) is necessary, concerned sub-department Technical Manager / Quality Manager makes changes and sends the document to the HOD/ Lab Director as applicable
- HOD/ Lab Director approves the document with a controlled stamp and issues to the Technical Manager/ Quality manager
- The previous version of the document becomes obsolete and is stamped as 'obsolete' and is retained by the Quality manager. (For Level 3 and 4 documents excluding Kit inserts, one copy is retained till the next audit, obsolete kit inserts are retained till the next audit) See document retention below



All level 1, 2 and 3 documents are reviewed and amended yearly, and the amendments are clearly noted on the amendment page. After 20 significant amendments, the issue may be changed. Temporary amendments may be done with a pen. re-issue / typed versions should be printed annually.

The following or their designees are responsible for document preparation and to approval.

DOCUMENT	PREPARATION	APPROVAL AUTHORITY
Quality Policy	Quality Manager	Lab Director / Medical Superintendent
Quality Manual	Quality Manager	Lab Director / Medical Superintendent
Quality System Processes	Quality Manager	Lab Director / Medical Superintendent
Standard Operating Procedures	Technical Manager	HOD
WDL/ Bench Aids	Quality Manager	HOD
Formats	Quality Manager	HOD

Ref.: M-57: Master Log, M-18 (Obsolete Files and Formats)



Annexure 9

Example of an SOP

SOP of GLUCOSE TESTING

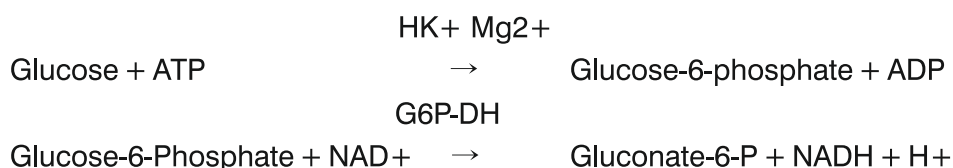
a. PURPOSE

Enzymatic UV test (hexokinase method) for the quantitative determination of glucose in human serum, plasma, urine, haemolysate and cerebrospinal fluid on Beckman Coulter AU analysers. For in vitro diagnostic use only.

b. PRINCIPLE OF TEST

Glucose is phosphorylated by hexokinase (HK) in the presence of adenosine triphosphate (ATP) and magnesium ions to produce glucose-6-phosphate and adenosine diphosphate (ADP). Glucose-6-phosphate dehydrogenase (G6P-DH) specifically oxidises glucose-6-phosphate to gluconate-6-phosphate with the concurrent reduction of NAD^+ to NADH. The increase in absorbance at 340nm is proportional to the glucose concentration in the sample.

CHEMICAL REACTION SCHEME



c. PERFORMANCE CHARACTERISTICS

Linearity

The test is linear within a concentration range of 10 – 800 mg/dL for serum, plasma, haemolysate and CSF.

The test is linear within a concentration range of 1 – 800 mg/dL for urine.

Precision (As claimed by manufacturer)

The following data was obtained on 3 serum pools analysed over 10 days.

n = 60 within Run, Serum, CV% 1.25, 0.97, 1.11

Precision verified by the laboratory with plasma; reproducibility 1%

Intermediate precision verified by the laboratory using quality controls; L1- 1.5% and L2- 1.2%.

Method Comparison

Patient serum samples were used to compare this Glucose assay OSR6121 on the AU600 against another commercially available glucose assay. Results of linear regression analysis were as follows:

$$r = 0.998 \text{ } n = 117$$

Patient urine samples were used to compare this Glucose assay OSR6121 on the AU2700 against another commercially available glucose assay. Results of linear regression analysis were as follows:

$$r = 1.000 \text{ } n = 120$$

d. SAMPLES**Plasma**

Sample Stability: Sample stability has been validated in the lab for a period of 24 hours at 2-8°C. The sample storage period of 1 day has been decided as the routine protocol and NABL 112

Sample requirement: Minimum sample volume required is 2 .0 ml in grey tubes containing sodium flouride.

Sample rejection: Haemolysed or lipeamic serum, inadequate sample volume, unlabeled sample

Urine: Fresh, random collections are recommended for urine specimens. Stable in urine for 2 hours when stored at 2-25°C. Analyze as soon as possible.

Cerebrospinal fluid: Process immediately to avoid falsely low results.

e. PATIENT PREPARATION

Fasting glucose: 8-10 hours of fasting

Post prandial: 2 hours post meal

Random: any time

Loading tests: As given below

f. TYPE OF CONTAINER

Blood samples should be collected into grey tubes containing fluoride. Other samples are accepted in sterile containers

g. EQUIPMENT and REAGENT REQUIREMENT:

EQUIPMENT: Beckman Coulter AU analyser, Fluoride tubes

REAGENT: AU 480 Enzymatic UV test (hexokinase method) kit



Final concentration of reactive ingredients:

PIPES buffer (pH 7.6)	≥ 2.0 mmol/L
ATP	24.0 mmol/L
NAD+	≥ 2.0 mmol/L
Mg2+	≥ 1.32 mmol/L
Hexokinase	2.37 mmol/L
G6P-DH	≥ 0.59 kU/L
Preservative	≥ 1.58 kU/L

Reagent Preparation

The reagents are ready for use and can be placed directly on board the instrument.

Storage and Stability

The reagents are stable, unopened, up to the stated expiry date when stored at 2-8°C. Once open, reagents stored on board the instrument are stable for 30 days.

h. SAFETY:

Exercise the normal precautions required for handling all laboratory reagents.

To avoid the possible build-up of azide compounds, flush waste-pipes with water after the disposal of undiluted reagent.

Dispose of all waste material in accordance with BMW guidelines.

The material used as a calibrator or quality control should be handled as infectious and universal precautions to be followed.

i. CALIBRATION

Calibrator required

Plasma/CSF: Use System Calibrator Cat. No. 66300.

Urine: Use Urine Calibrator Cat. No. ODC0025.

Calibration frequency

As per manufacturer's instructions recalibration is lot/lot or every 30 days, or when the following situations occur:

- Change in reagent lot or significant shift in control values;
- Major preventative maintenance was performed on the analyzer or a critical part was replaced. However, daily or bottle to bottle calibration may be done as per the discretion of the lab manager

Calibrator Preparation

1. Allow the vial to equilibrate to room temperature before opening to prevent condensation in the vial.
2. Tap the top of the vial before opening to dislodge any lyophilisate caught in the stopper. Always open the vial gently to prevent any loss of lyophilisate.



3. Add to the vial of fresh deionized water equilibrated to room temperature, (approx. 20°C). Use a calibrated pipette that can accurately dispense 5.0 mL - weigh if unsure.
4. Invert the vial 3 times and then leave to stand for 10 minutes. Dissolve the contents completely by gently mixing on a roller for 30 minutes. Do not shake the vial as this will cause foaming.
5. Continue mixing until the solution is homogeneous and all lyophilized material is reconstituted.
6. Record the date the vial was reconstituted on the bottle label. Store at 2-8°C.

Calibrator Stability

Store in aliquots at -20°C for 30 days

Traceability

The glucose values of both calibrators are traceable to the National Institute of Standards and Technology (NIST) Standard Reference Material (SRM) 965.

j. TESTING PROCEDURE

Follow the AU 480 user guide. Refer to the appropriate Setting Sheet for analyzer-specific assay instructions

k. QUALITY CONTROL:

Internal control:

2 levels of controls, Level 1 and Level 2 are to be run for every 75 patients. In addition, controls should be run with each new calibration, with each new reagent cartridge, and after specific maintenance or troubleshooting procedure as detailed in the AU 480 operating instructions manual.

Interpretation of QC is to be done as per protocol. All outliers; warning and rejection, corrective actions should be documented. CV % should be analyzed monthly for trends. Comparison with peer group to be maintained for biases

External controls: registered with EQAS- worldwide program

Interpretation of EQAS results to be done after every cycle. Root cause analysis and Corrective actions should be documented.

I. INTERFERENCE AND LIMITATIONS OF PROCEDURE

Results of serum studies conducted to evaluate the susceptibility of the method to interference were as follows

SUBSTANCE	Limit
Ascorbate	Interference less than 3% up to 20 mg/dL ascorbate
Icterus	Interference less than 10% up to 40 mg/dL bilirubin
Haemolysis	Interference less than 3% up to 5 g/L haemoglobin
Lipemia	Interference less than 10% up to 700 mg/dL Intralipid



m. CALCULATING RESULTS TO INCLUDE MEASUREMENT UNCERTAINTY

The expanded measurement uncertainty of glucose incorporating long term CVs and long term bias assessment using cumulative peer group data is around 3.2 %. The details of this will be given to the clinicians on request

n. BIOLOGICAL TEST INTERVALS:

Serum/Plasma (fasting)

Adults: 74 – 99 mg/dL

Children: 60 – 99 mg/dL

Urine

1 – 15 mg/dL

CSF

Adult: 40 – 70 mg/dL $\approx$ 60% of plasma value

Post prandial Glucose: $\leq$ 140 mg/dL

Oral Glucose Tolerance Test (OGTT) fasting and a sample drawn 2 hours after a 75-gram glucose load

Fasting Glucose value	Interpretation
From 70-99 *mg/dL	Normal fasting glucose
From 100* to 125 mg/dL	Impaired fasting glucose (pre-diabetes)
126 mg/dL and above on more than one testing occasion	Diabetes

2 hour value	Interpretation (Levels applicable except during pregnancy.)
Less than 140 mg/dL	Normal glucose tolerance
From 140 to 199 mg/dL	Impaired glucose tolerance (pre-diabetes)
Over 200 mg/dL on more than one testing occasion	Diabetes

*Upper limit of FBS as per AU 480 reference ranges, other values as per ADA norms

Criteria for the diagnosis of Diabetes Mellitus (ADA)	
Diabetes mellitus	Any of the following - Fasting plasma venous glucose $\geq$ 126 mg/dL 2-hour oral glucose tolerance test (OGTT) (with 75g glucose) plasma venous glucose $\geq$ 200 mg/dL - Random glucose $\geq$ 200 mg/dl
Impaired fasting glucose (IFG)	Fasting plasma venous glucose measurement 100*-125 mg/dL
Impaired glucose tolerance (IGT)	Both of the following - Fasting plasma venous glucose < 126 mg/dL 2-hour OGTT plasma venous glucose $\geq$ 140 mg/dL and < 200 mg/dL



Gestational Diabetes Screening: Glucose Challenge Test (Sample drawn 1 hour after a 50-gram glucose load)

1 hour value	Interpretation
Less than 140* mg/dL	Normal screen
140* mg/dL and over	Abnormal, needs GTT (see below)

* A cutoff of 130 mg/dL if used identifies 90% of women with gestational diabetes, compared to 80% identified using the threshold of 140 mg/dL

Gestational Diabetes Diagnostic: OGTT (Fasting + 2 samples drawn after 75-gram* glucose load).

Sample Type	Target
Fasting (prior to glucose load)	92 mg/dL
1 hour after glucose load	180 mg/dL
2 hours after glucose load	153 mg/dL
Interpretation: If any value exceeds the target level, gestational diabetes is diagnosed	

o. REPORTABLE RANGE: 10 to 1600 mg/dL

p. DETERMINING RESULTS WHEN THE RESULT IS NOT WITHIN MEASURABLE RANGE

LINEARITY: The test is linear within a concentration range of 10 – 800 mg/dL for serum, plasma, haemolysate and CSF. The test is linear within a concentration range of 1 – 800 mg/dL for urine.

Limits of Detection (LOD) verified in the lab: 20-800 mg/dL

For samples with concentration less than 20 mg/dL; the result should be reported as < 20 mg/dL. For samples with concentration more than 800 mg/dL, the plasma should be diluted 1:1 and multiplied. The system performs all calculations internally to produce the final reported result. AU 480 does not calculate the final result for sample dilutions made by the operator. In these cases, the result produced by the instrument must be multiplied by the dilution factor before reporting the final result.

q. PANIC ALERT VALUES:

Plasma Glucose	Low	High
Adult	40 mg /dL	450 mg /dL
Children	46 mg/dL	445 mg/dL
Newborn	30 mg/dL	325 mg /dL

r. INTERPRETATION:

In the fasting state, blood sugar levels are regulated by the liver, which ensures that levels are maintained within precise limits. The rapid and precise manner in which fasting blood sugar levels are regulated is in marked contrast to the rapid increase in blood sugar, which occurs during ingestion of carbohydrates. A fall in blood glucose to a critical level (approximately 40



mg/dL) leads to dysfunction of the central nervous system. This manifests as hypoglycaemia, and is characterised by muscle weakness, lack of coordination and mental confusion. Further decrease in blood glucose levels leads to hypoglycaemic coma. Blood glucose concentrations show intra-individual fluctuations, which are dependent on muscular activity and the time interval since food intake. These fluctuations are increased further where there is dysregulation, such as what occurs in a number of pathological conditions in which blood glucose may be elevated (hyperglycaemia) or depressed (hypoglycaemia). Hyperglycaemia most commonly occurs as a result of a deficiency in either the amount or efficiency of insulin, a condition known as diabetes mellitus. This disease is characterized by the elevation of blood glucose to such an extent that the renal threshold is exceeded and sugar appears in the urine (glycosuria). Blood glucose measurement is used as a screening test for diabetes mellitus, where there is suspected hyperglycaemia, monitoring of therapy in diabetes mellitus, evaluation of carbohydrate metabolism, for example in gestational diabetes acute hepatitis, acute pancreatitis and Addison's disease. Hypoglycaemia is associated with a range of pathological conditions including neonatal respiratory distress syndrome, toxemia of pregnancy, congenital enzyme defects, Reye's syndrome, alcohol ingestion, hepatic dysfunction, insulin-producing pancreatic tumours (insulinomas), insulin antibodies, nonpancreatic neoplasms, septicemia and chronic renal failure.

CSF glucose may be low or undetectable in patients with acute bacterial, cryptococcal, tubular or carcinomatous meningitis, or in cerebral abscess, probably due to consumption of glucose by leucocytes or other rapidly metabolising cells. In meningitis or encephalitis due to viral infections, it is usually normal.

s. POTENTIAL SOURCES OF VARIATION

The quickness of separation of the red blood cells from the plasma by centrifugation is a critical element, because it is estimated that plasma glucose levels are reduced ~ 10 mg/dl per hour by consumption of glucose in the red blood cell's glycolytic pathway. Thus, a plasma sample that was immediately centrifuged would be expected to have a significantly different glucose than one centrifuged many hours later.

Intra individual variation of plasma glucose have been reported to ~ 14%

If fasting can include both morning and afternoon, this biological variation is even larger, because morning fasting blood glucose is higher than afternoon fasting blood glucose

t. REFERENCES.

1. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics by Carl A. Burtis, Edward R. Ashwood, David E. Bruns, Fourth Edition, 2006, Table - 56.3 Page No 2317, 868-875
2. AU 480 Chemistry Information Manual
3. ADA Guidelines 2013



Glossary

Audit	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
Checklist	A list used to ensure all important steps or actions in an operation have been taken. Checklists contain items important or relevant to an issue or situation
CLSI	Clinical and Laboratory Standards Institute. US-based institute that uses consensus process in developing standards.
Continual Improvement	The cornerstone of quality management systems, allows the laboratory to gain insights from setting objectives, monitoring through audit and management review, addressing complaints and nonconformities, and performing client satisfaction surveys. A recurring activity to increase the ability to fulfil requirements: Plan, Do, Check, Act.
Continuous Quality Improvement (CQI)	Continuous Quality Improvement (CQI) A philosophy and attitude for analysing capabilities and processes and improving them repeatedly to achieve the objective of customer satisfaction
Controlled Documentation	A system for maintaining and ensuring the proper use of time or version sensitive documents.
Document	Information and its supporting medium; digital or physical. ISO identifies five types of documents: specifications, quality manuals, quality plans, records, and procedure documents. See Normative and Standard documents.
Documentation	Written material defining the process to be followed.
Flowchart	A graphical representation of the flow of a process. A useful way to examine how various steps in a process relate to each other, to define the boundaries of the process, to identify customer/supplier relationships in a process, to verify or form the appropriate team, to create common understanding of the process flow, to determine the current "best method" of performing the process, and to identify redundancy, unnecessary complexity and inefficiency in a process.

Form	A paper or electronic document on which information or results are captured; once completed becomes a record.
Indicators	Established measures used to determine how well an organization is meeting its customers' needs as well as other operational and financial performance expectations
ISO Standards	A set of international standards providing guidance for quality in manufacturing and service industries; developed to help companies effectively document the quality system elements to be implemented to maintain an efficient quality system. The standards, initially published in 1987, are not specific to any particular industry, product or service; broad applicability, many kinds of organizations can use.
Job Aids	Job Aids are procedure guides with varying levels of procedure guidance used to shape behaviour (when used for training purposes) or direct behaviour (when used to elicit exact performance without prior intervention). A JA is a “storage place” for information other than human memory.
NABL	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.
PDCA	Plan, Do, Check, Act (Quality improvement tool). A checklist of the four stages which you must go through to get from ‘problem-faced’ to ‘problem solved’. See Deming Cycle
Process Approach	A management strategy used by managers to control the processes that make up their Quality Management Systems, the interaction between these processes.
Quality Management Standards	Quality Management Standards (such as ISO 15189) are a series of policy statements. Required statements include the term “shall”. Full compliance with the standard requires that all “shall” statements are implemented. Were the laboratory to be inspected to ensure compliance with the standard, the auditor or inspector would expect to see evidence that each required “shall” policy was being met. “Shall” statements are often supplemented by notes or comments that often contain examples or statements using the term “should”. These statements are intended to give guidance on what would be considered as reasonable activities, content, or structure to demonstrate that the “shall” statement is being followed. The organization is not required to meet all the comments, suggestions or recommendations included within these notes or commentary.
Quality Management system (QMS)	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



Quality Record	Quality Record Objective evidence which shows how well a quality requirement is being met or how well a quality process is performing. It always documents what has happened in the past
Standard document	A document established by consensus, and approved by a recognized body, that provides, for common and repeated use, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order
Total Quality Management	Any management system that addresses all areas of an organization, emphasizes customer satisfaction, and uses continuous improvement methods and tools.
Verification	Verification Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.



Abbreviations

QMS	:	Quality Management System
NABL	:	National Accreditation Board for Testing and Calibration Laboratories
MSDS	:	Material Safety Data Sheet
QSP	:	Quality System Procedures
PDCA	:	Plan, Do, Check, Act (Quality Improvement Tool)
CLSI	:	Clinical and Laboratory Standards Institute
MR	:	Management Representative
QC	:	Quality Control
PT	:	Proficiency Testing
PTS	:	Proficiency Testing Schemes
EQAS	:	External Quality Assurance Scheme
SOP	:	Standard Operating Procedure
CQI	:	Continuous Quality Improvement
ISO	:	International Organization for Standardization
EQA	:	External Quality Assessment
ISO 9000	:	International Standards For Quality. Fundamentals And Vocabulary Document
LQM	:	Laboratory Quality Management
QA	:	Quality Assurance
QM	:	Quality Management
QSE	:	Quality System Essentials
TQM	:	Total Quality Management