Quality Manual Development Course

Contents

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Quality Manual Development Course

Introduction

Welcome

Course Description

This course describes the purpose and key elements of a quality manual that meets ISO 9001 and ISO 15189 requirements. The course will provide examples drawn from quality manuals that meet these requirements. It will also explain the development process for such a manual.

Introduction by Caroline Maurer

Objectives

After completing this course, participants will be able to:

- Identify the audiences and purposes of a quality manual
- Identify the necessary elements of a quality manual
- Describe possible structures of quality manuals
- Develop a quality manual
- Align quality policy, quality objectives, and quality metrics

Course Length

Approximately 1-2 hours

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Disclosure Statement

None of the authors, planners, or reviewers of this course have any financial relationships to disclose.

Quality Manual Development Course

Course Text

This attachment provides the text of this course in easily printable form.

Quality Manual Development Course Text

Continuing Education (CE) Credit

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To claim credit, follow the steps at the following page in this course: Course Resources/Continuing Education (CE) Credit.

Note: You must claim credit while your one-year course license is active.

Meet the Presenters

Caroline Maurer is the program director of CAP 15189. She brings 20 years of experience in health care operations for medical laboratories and other diagnostic services.

David Wolfe is a lead assessor for the CAP 15189 program. In his career in ISO 9001 and medical device auditing, he has conducted more than 900 audits.

Background

What is a quality manual?

A quality manual is a document that describes the quality management system and its essential elements.

What is a quality management system?

What is the purpose of a quality manual?

Here are some of the purposes:

David Wolfe on the utility of a process-based manual

- Answers key questions:
  - What is "quality" for us and for our laboratory?
  - How do we attain it?
  - How do we run our laboratory?
- Provides a high-level overview of the quality management system
- Provides an "index" or "card catalog" of key documents, so managers and staff can find key documents and other pieces of information when needed
- Shows how the organization conforms to specific standards (eg, ISO 15189) and provides a framework for assessors to confirm compliance
- Provides a training and orientation tool for new employees who perform laboratory testing

Who is the audience of the quality manual?

The table below shows the different audiences and how the manual benefits them.

Audience	How It Benefits Them
Testing Personnel, Support Staff	• Source of information on how the laboratory works • Index of key processes and procedures
Managers, Supervisors	• Tool for training and orienting new employees • Summary of key processes and how these are performed and measured
Administrators, Executives	• Tool for marketing and contract negotiation; helps potential customers understand commitment to quality and depth of the quality management system
External Auditors	• Outlines the quality management system and key documents so external auditors can have a basis for planning and conducting the audit
Internal Auditors	• Tool for gaining understanding of overall quality management system as well as processes in areas other than their own so internal auditors can prepare for process audits

Is an ISO-based quality manual the same as a "quality plan" that meets CLIA or CAP/LAP standards?

An ISO-based quality manual is broader in scope than a "quality plan." It helps to meet the requirements of CLIA and CAP/LAP, but also goes beyond them.

"Quality plans" describe the objectives and elements of the quality program, which may or may not be based on a standard such as ISO. (See CAP Laboratory General Checklist, Quality Management section.)

An ISO-based quality manual is an index to a system that must contain specific elements as described by the ISO standard. For example, the ISO 9001 and 15189 standards require that the system contain the following elements:

- A quality policy that is linked to quality objectives and measures
- Documentation of the key processes of the laboratory, and how they interact with each other and their supporting procedures
- Specific quality monitoring systems such as internal auditing and complaint handling
- Specific continual improvement systems such as management review

Who develops the quality manual?

The quality manual is typically a joint effort between top management and the quality manager.

Top management is responsible for:

- Developing and implementing the quality management system
- Ensuring that:
    - Quality objectives are established
    - Periodic management reviews are conducted
    - Resources are available to attain the quality objectives and meet customer needs

The quality manager is responsible for developing a quality manual that reflects the system and keeping that quality manual up to date.

Once the manual is developed, both the quality manager and top management ensure that all laboratory personnel:

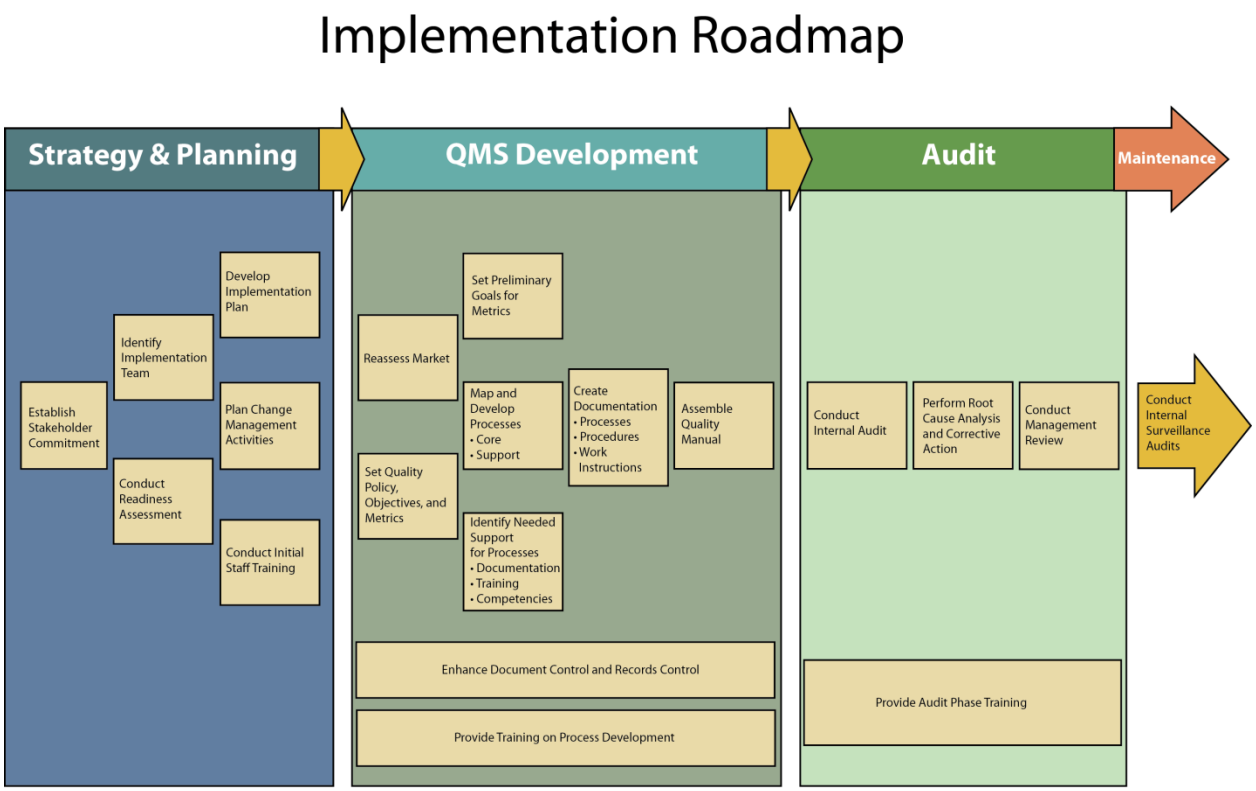
- Have access to the quality manual
- Have been instructed on the use and application of the quality manual and the referenced documents

When does a laboratory develop a quality manual?

You should develop your quality manual *after* you have developed and refined the core and support processes of your laboratory.

Sequentially, assembling the quality manual should be the ***last*** thing that happens in the "QMS Development" phase of your implementation.

Click on the graphic below to see the steps in QMS implementation.



High Level QMS Implementation Roadmap (PDF)

Note: The CAP QM*Ed* course QMS Implementation Roadmap explains each step in this diagram in more detail.

When done this way, the manual describes the specifics of your particular laboratory.

By contrast, some laboratories try to create the manual at the outset, perhaps buying and adapting a sample manual off of the internet. These "generic" quality manuals are very often abstract and disconnected with the particular laboratory. They are of little use to anyone inside or outside the laboratory.

Elements and Structure

Elements of the Manual

Here is a listing of the required elements. The rest of this section will elaborate on each element.

1. The organization's quality policy, with corresponding quality objectives and metrics
2. Scope of laboratory services
3. Structure of documentation
4. Key processes and supporting procedures
5. A presentation of the organization and management structure of the laboratory
6. A description of roles and responsibilities of management with regard to quality

The remainder of this section contains a description of each of these six elements.

1. The organization's quality policy, with corresponding quality objectives and metrics

According to ISO 15189, the quality manual needs to include a quality policy. The policy needs to be consistent with the quality objectives, which should be measurable. A good practice is to include these elements in table form, so that the reader can easily see the link between them.

Here is an example for a laboratory providing oncology services:

Quality Policy:

"To ensure accurate and timely examinations and services for our oncology patients and health care providers and to continuously meet or exceed the stated or implied expectations of our clients and stakeholders."

Example Objectives & Metrics

Elements of quality policy	**Corresponding quality objectives**	**Corresponding Metrics**
Accurate examinations and services	Maintain or improve scores in PT testing	Proficiency Testing (PT) results
	Reduction in amended reports	Number or percentage of amended reports
	Reduction in laboratory accidents (eg, lost in transport, quantity not sufficient)	Number of laboratory accidents
Timely examinations and services	Timely test results	Turn Around Time (TAT)
Meet or exceed expectations of customers and stakeholders	Improved customer survey scores	Survey results TAT for customer complaints Improvement in satisfaction scores or percentile

Part of your challenge here is to develop a set of metrics that will be practical to collect and truly useful to your laboratory.

David Wolfe on choosing metrics

2. Scope of services

Defining scope of services means saying what you're here to do, naming who you serve, and defining the disciplines in which your laboratory operates. For laboratories in the U.S., this is the same information that appears on the CLIA license and/or CAP records (activity menu).

For a regional hospital laboratory, the scope of services might include the following:

Disciplines

- Hematology
- Chemistry
- Transfusion services
- Microbiology
- Anatomic Pathology

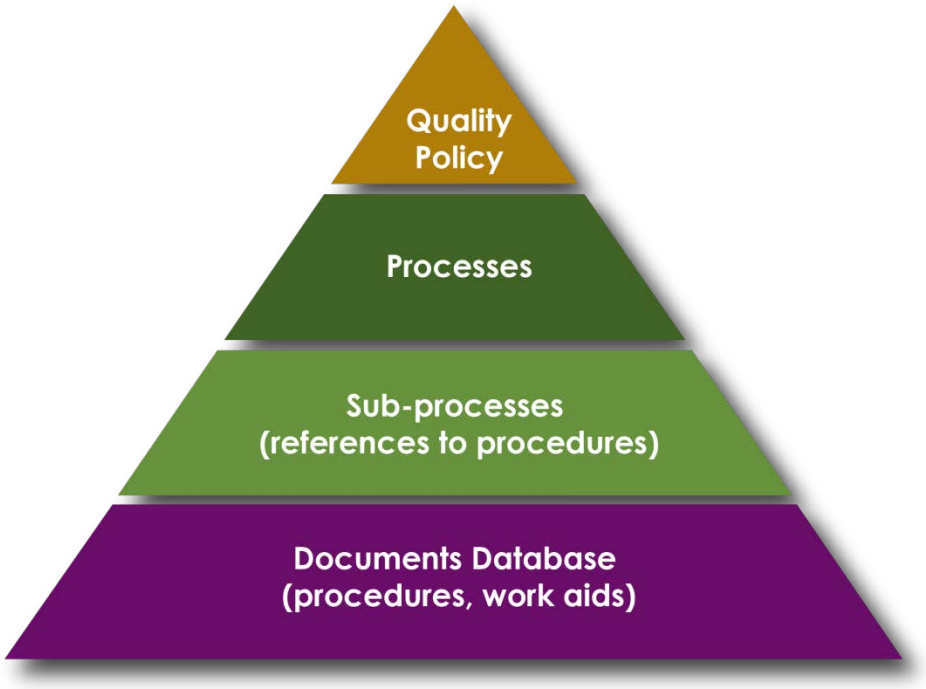
Patients/customers served

- Community (outpatients)
- Physicians' offices (reference work)
- Hospital (in-patients)
- Other hospitals (reference work)

3. Structure of documentation

The quality manual should explain or diagram how the various kinds of documents relate to each other. Ideally, documents are structured hierarchically, and layered, with high-level process documents at the top, more detailed sub-processes below them, and step-by-step procedures and work aids at the bottom. This is known as the document pyramid concept.

Here is a sample document structure:



4. Key processes and supporting procedures

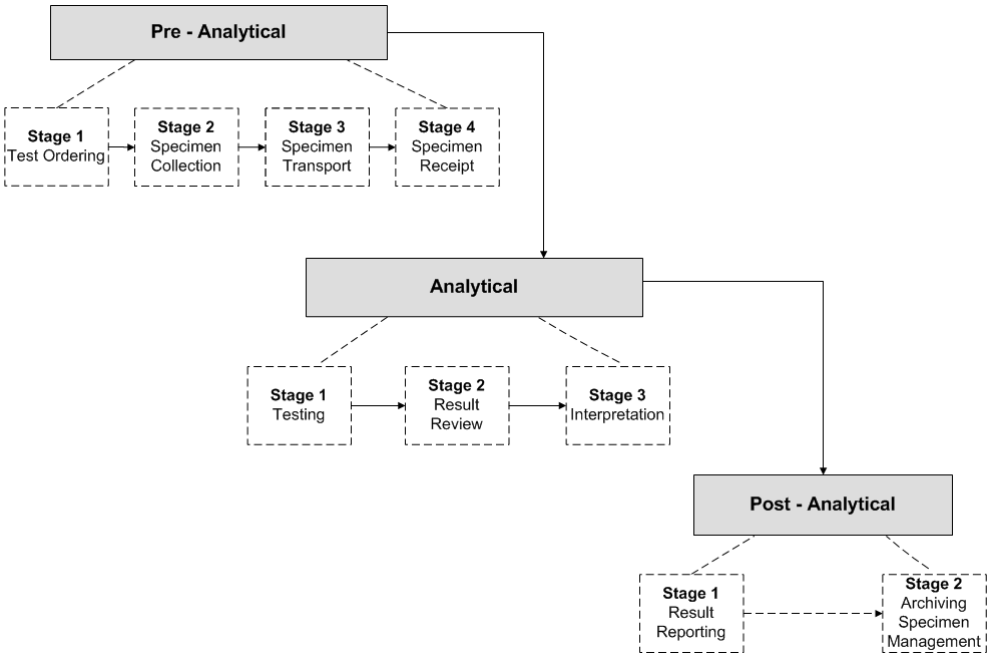
The ISO standard requires that the quality manual "include or make reference to" key processes and supporting procedures.

This means the manual does not need to serve as a big, thick repository of all procedures. In fact, it works better if the quality manual serves as an "index" or "card catalog" of the key processes and procedures, helping users to find them.

A useful approach is to provide the high-level processes of the laboratory, and then create sub-process tables that refer to the supporting procedures.

David Wolfe on linking QMS and document control

Here, for example, is a diagram of the core processes and sub-processes of a hospital laboratory.

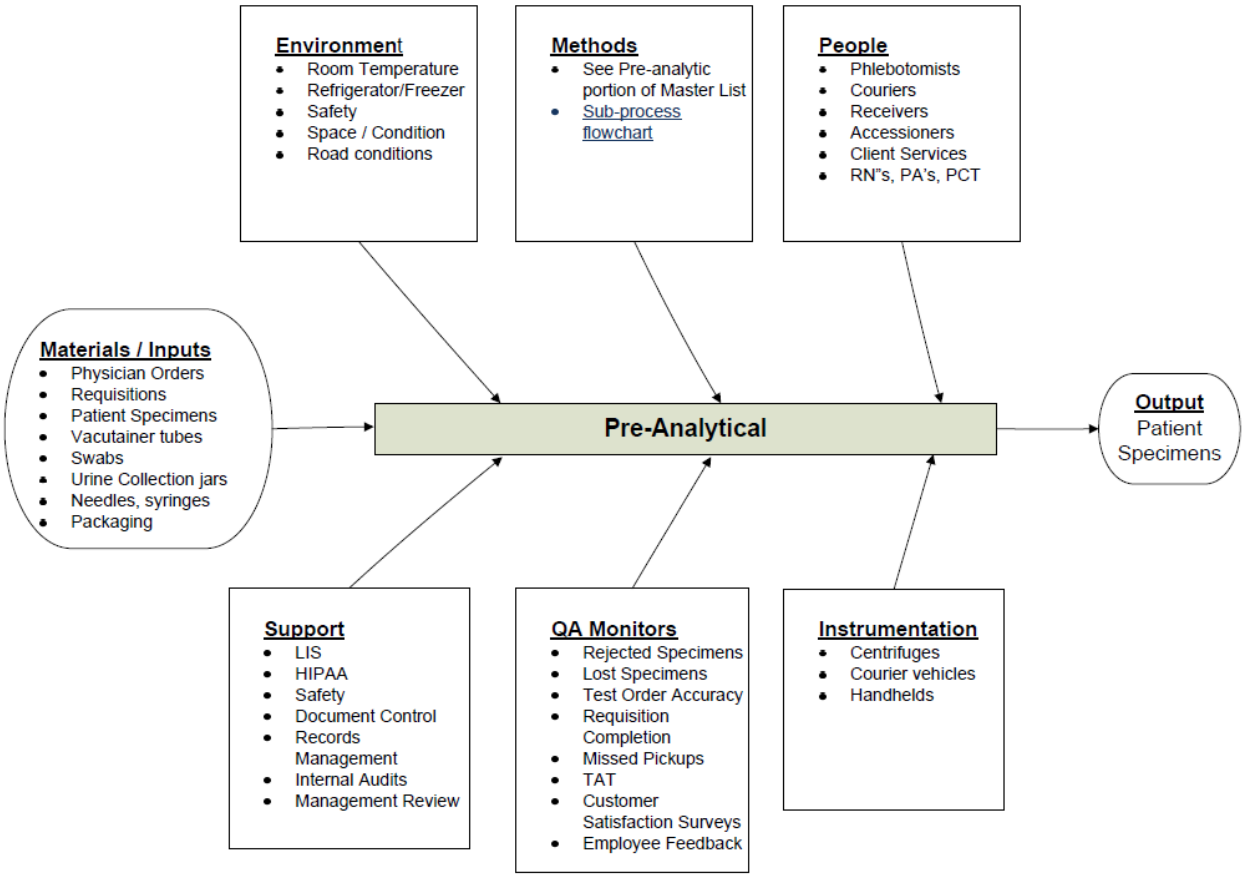


Core Processes and Sub-Processes (PDF)

Below is a table that supplies more detail about the Post-Analytical/Result Reporting sub-process. Notice that the table refers to the specific procedures that are needed to do the work correctly.

Step	What	Who	Related Documents
1	Enter results into the Laboratory Information System (LIS) manually, or via instrument interface	• Technologists • Send-out personnel	• PO.532 Reporting Patient Results • ADM.165 Computer Downtime Plan • ADM.157 Computer Problem Flowchart
2	Check for correctness	• Technologists • Send-out personnel	• PO.560 Verifying Results in Laboratory Information System

This hospital laboratory also created "fishbone" diagrams to show inputs and outputs, and factors that influence quality in each process. The diagram lists key procedures for specific sub-processes under "Methods" in the diagram below.



Fishbone Diagram (PDF)

Providing this kind of information also satisfies the ISO requirement that the laboratory "determine the sequence and interaction of (the) processes" in their laboratory. When processes are mapped in terms of inputs and outputs, and when factors that influence quality are documented, it is easier to improve processes.

Process maps show the "handoffs" from one person or group to the next. An interaction occurs when a "deliverable" (something of value) moves from one person or group to another. It is helpful to document the following things:

- What happens to deliverables?
- What does the next person do to accept that deliverable or input?

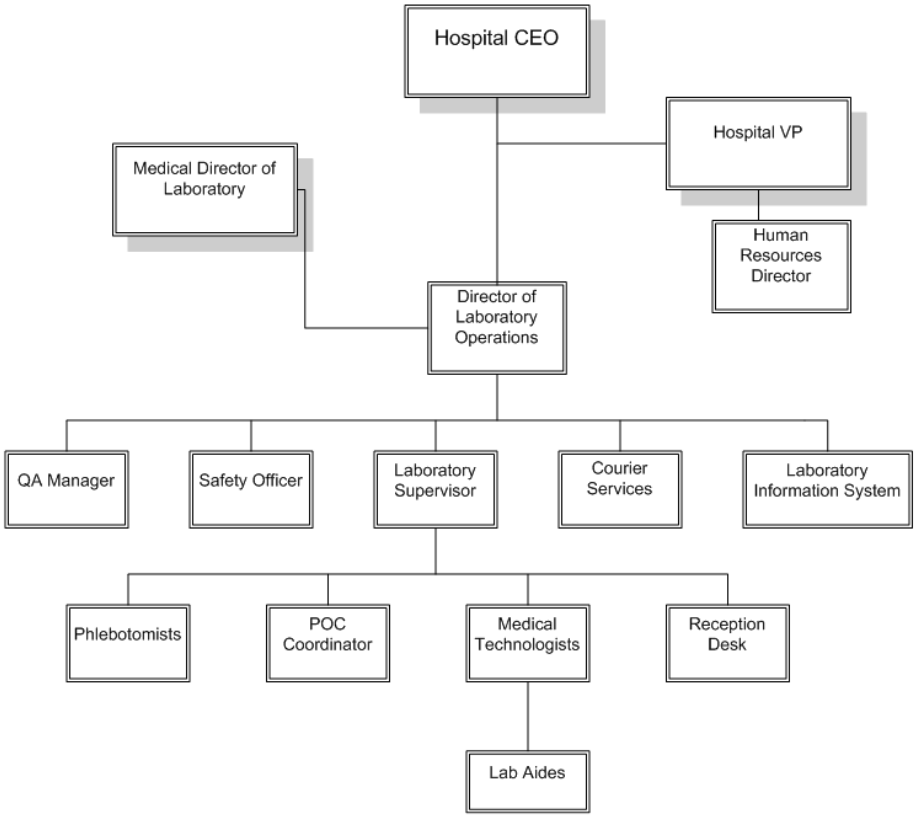
Once we understand the answers to these questions we have a basis for improving the handoff. We can store materials and information in a way that makes the handoff easy (for example, put material in freezer; put information in folder, send as email, or save a spreadsheet to a network folder).

When quality manuals are structured this way, there is no need to include the specific procedures referred to in the manual. The manual can tell people where to find them, or link to them electronically. If the laboratory is operating with a paper document control system, the quality manual can refer to a master document log. If the laboratory is operating with an electronic document control system, the quality manual can link to the home page of that electronic system, which allows sorts and searches for different types of tests.

This approach may seem intuitive but few laboratories implement it.

5. A presentation of the organization and management structure of the laboratory

The important thing here is to show lines of decision making. Show that your laboratory has a basis for objective decision making. Show that the way decisions are made do not create conflicts of interest. For example the person in charge of the quality management system should not be responsible for testing processes in the laboratory. This structure can be easily presented as an organizational chart.



6. A description of roles and responsibilities of management with regard to quality

This section contains a description of how manager-level personnel in the laboratory contribute to quality. It explains their respective roles for implementing and maintaining the quality management system.

If the job descriptions in the Human Resources department database provide this information, then it may be sufficient to link to the HR database. But job descriptions often do not contain this

information, and contain other elements that are not pertinent to the roles of that position regarding quality. For this reason, it may be better to craft specific quality-related role descriptions.

This table shows that quality is not just the responsibility of the Quality Manager. Others share the responsibility as well.

Position	Roles/Responsibilities
Medical Director of Laboratory	Is responsible for the clinical aspects of laboratory testing which includes: approval of the new tests, test procedures, reference ranges, report format, clinical interpretation, and consultation.
Director of Laboratory Operations	Is responsible for activities involved in laboratory operation such as testing, reporting, logistics, facilities, and environmental health and safety. This position oversees the laboratory operation staff, laboratory equipment, and laboratory testing supply resources.
Quality Assurance Manager	Is responsible for developing, implementing, monitoring, documenting and continuously improving an overall Quality Management System which includes Quality Control, Quality Assurance and Quality Improvement, Quality Metrics, Document Control, Internal and External Audit, Corrective Action/Root Cause Analysis, Management Review, Proficiency Testing, Staff Training/Competency, and Regulatory Compliance activities.
Laboratory Supervisor	Is responsible for supervising the activities of the laboratory and ensuring its smooth and efficient functioning. Performs standard biological, microbiological, and chemical tests in all areas of the medical laboratory to assure delivery in an accurate and timely fashion using proper safety precautions. Tests new and improved laboratory methods and procedures. Trains or supervises training of other lab staff. Evaluates quality control and quality assurance statistics and modifies manuals as needed. Develops a budget for the laboratory and maintains control of lab costs. Enforces safety procedures and consults with other supervisors about these issues. Consults with state lab staff about local problems and interaction.

Structure of the Manual

There are a number of ways you can structure your manual:

- According to external categories such as ISO clauses or Quality System Essentials (QSE) sections
- According to the processes of your laboratory

According to ISO clauses/Quality System Essentials (QSEs)

Many laboratories make the manual into a list of "policies" that essentially restate the ISO standard clauses or QSEs, asserting that the laboratory does all of these things. But how useful is a manual that contains a restatement of clauses from regulatory standards?

The ISO standards and QSEs are convenient ways of categorizing quality requirements. They do not correspond to the way the laboratory works. They do not describe how work flows through your organization, and how your quality policy and plans translate into action.

For these reasons, they are foreign classification systems for front line staff. Quality manuals structured this way are unlikely to meet the needs of front line staff. You can educate your staff in these foreign schemes, but they will always be uncomfortable, external, and outside the laboratory.

David Wolfe on bad manuals

According to Processes of Your Laboratory

In this approach, the focus of the manual is on the processes of the laboratory. This is the approach we recommend – a process-based manual. It makes the structure of the quality manual both easy and comfortable for your audience.

The process maps and tables show how the system is supposed to work. In doing this, *the laboratory is in fact setting forth a policy of how it should operate.* A policy is, by definition, a "statement of overall intentions, endorsed by management and chosen from among alternatives to guide and determine present and future decisions."

The laboratory communicates its overall intentions for the system by providing:

- A succinct "quality policy"
- The quality objectives and metrics
- The processes and how they interact to support the quality policy and quality objectives
- Specifics about laboratory organization and management
- The specific quality standard (eg, ISO 15189) with which the laboratory complies

These elements of a quality manual set forth a policy of how the laboratory works and ensures quality.

Rather than restating ISO clauses in the quality manual, a better approach is to simply state as part of the quality policy that the laboratory complies with a specific standard (eg, ISO 15189).

Implementation

Best Practices

Here are some best practices for developing your manual:

1. Use simple and plain terms.

Recognize that your readers may have English as their 2nd language; write simply and clearly.

Instead of saying...	Say...
"...adequate resolution of issues..."	"...fixing customer problems so customers are happy..."
"...service realization..."	"...delivering the service to the customer..."

Many manuals are filled with bureaucratic, pseudo-sophisticated language.

Here is a sample paragraph from an actual quality manual.

> ". . . The organization shall develop, implement and maintain adequate procedures, work instructions and/or workflows that will ensure the requirements of the customer and the organization relative to product realization are met. Consideration shall be given to:
> - The provision for adequate resources;
> - Suitable stages during product realization where customer property shall be verified for conformance to established acceptance criteria and customer requirements as defined in the Service Order document and section 8.2.4 of this manual."

What does this really say? Whatever it is, it could be – and needs to be – said more clearly and simply.

2. Make the document easy to scan and interpret; consider using Information Mapping methods.

Many quality manuals are written in paragraph form. This is the way many of us were taught to write in school, but it is not well suited for business purposes. Paragraphs (especially long paragraphs) make it hard to find information. Readers have to read every word, because the document is hard to scan.

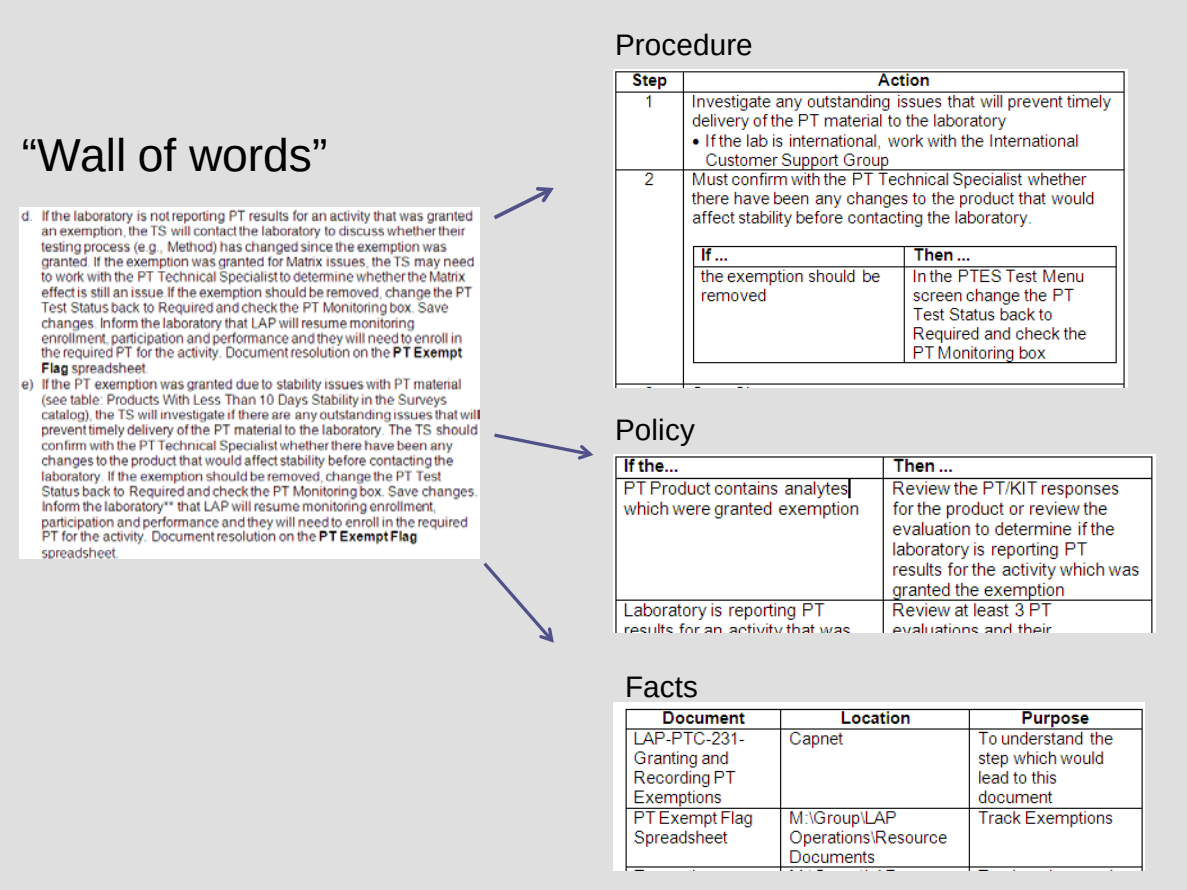
Some manual writers make use of Microsoft Word's automatic outlining feature. An outline is easier to scan, but often forces the text into an unnatural structure. Outlines may work well when planning essays or term papers, but they are not the best way to communicate laboratory policies, processes, and procedures.

Information Mapping methods use small, labeled "blocks" of information as the basic unit of communication. They also use tables to make the structure clear and say things in as few words as possible.

Consider the following process table. Imagine writing this in either paragraph or outline form. Neither would work well. Using a table eliminates needless words.

Step	What	Who	Related Documents
1	Generate labels	• Laboratory secretary • Phlebotomist • Technologist • Ward Clerk - ED	• Test Request and Ordering
2	Identify patient	• Phlebotomist • Technologist • Other appropriately-trained health care staff	• Patient and Specimen Identification • Becker-Maurer Laboratory Directory of Services • Specimens Requiring Chain-of-Custody

Information Mapping methods can take a "wall of words" written in paragraph or outline form and translate it into well-organized, easy-to-scan blocks of information.



Transforming a "Wall of Words" (PDF)

Pitfalls

Here are some common pitfalls related to *content* of a quality manual:

- Bureaucratic, pseudo-sophisticated language
- Omissions
  - No description of processes and their interactions
  - No linking of metrics, objectives, and policy
- Lack of "layering" of documentation. Quality manual goes into too much detail, includes detailed procedures, rather than staying at a high level and referring to these documents.
- Poor job of layering – the document should clearly show the high-level processes, sub-processes, and procedures, but with some manuals there is an unorganized collection of documents from many different levels
- Unnecessary content – with many manuals, there is so much unnecessary material that staff find it difficult to find what they need

Here are some common pitfalls related to the *process* of developing a quality manual:

- "Instant pudding" approach – sometimes laboratories view the quality manual as an easy task that should not take long. They throw something together quickly.
- Using a template from a vendor, instead of basing the manual on laboratory-specific operations

Plan for Development of Process-based Manual

A quality manual cannot be developed in isolation from the rest of the quality management system. Here are the main steps that are necessary for creating your quality manual:

1. Develop your quality policy, objectives, and metrics.

The first phase of QMS development involves analyzing the market you want to serve, deciding what your value proposition is, and how you will deliver an excellent product to your chosen market.

Your scope of services, as well as your quality policy and objectives will flow from this work.

David Wolfe on making money

Your quality policy is a general statement of what the laboratory wants to accomplish in terms of quality. But you need to translate this general statement into more specific, measurable terms. By making the policy cascade into the objectives and metrics, you clarify exactly what you want to accomplish. Consider using a table like the following:

Elements of quality policy	**Corresponding quality objectives**	**Corresponding Metrics**
Accurate examinations and services	Maintain or improve scores in PT testing	Proficiency Testing (PT) results
	Reduction in amended reports	Number or percentage of amended reports
	Reduction in laboratory accidents (eg, lost in transport, quantity not sufficient)	Number of laboratory accidents
Timely examinations and services	Timely test results	Turn Around Time (TAT)

Your laboratory has most likely developed a quality policy and chosen metrics. But you will still want to revisit this, and make sure there is a logical flow from the quality policy to the quality objectives and to the metrics.

2. Develop and refine your processes.

In this phase you will map out your processes. You may also apply tools such as Lean and Six Sigma to refine and improve the process.

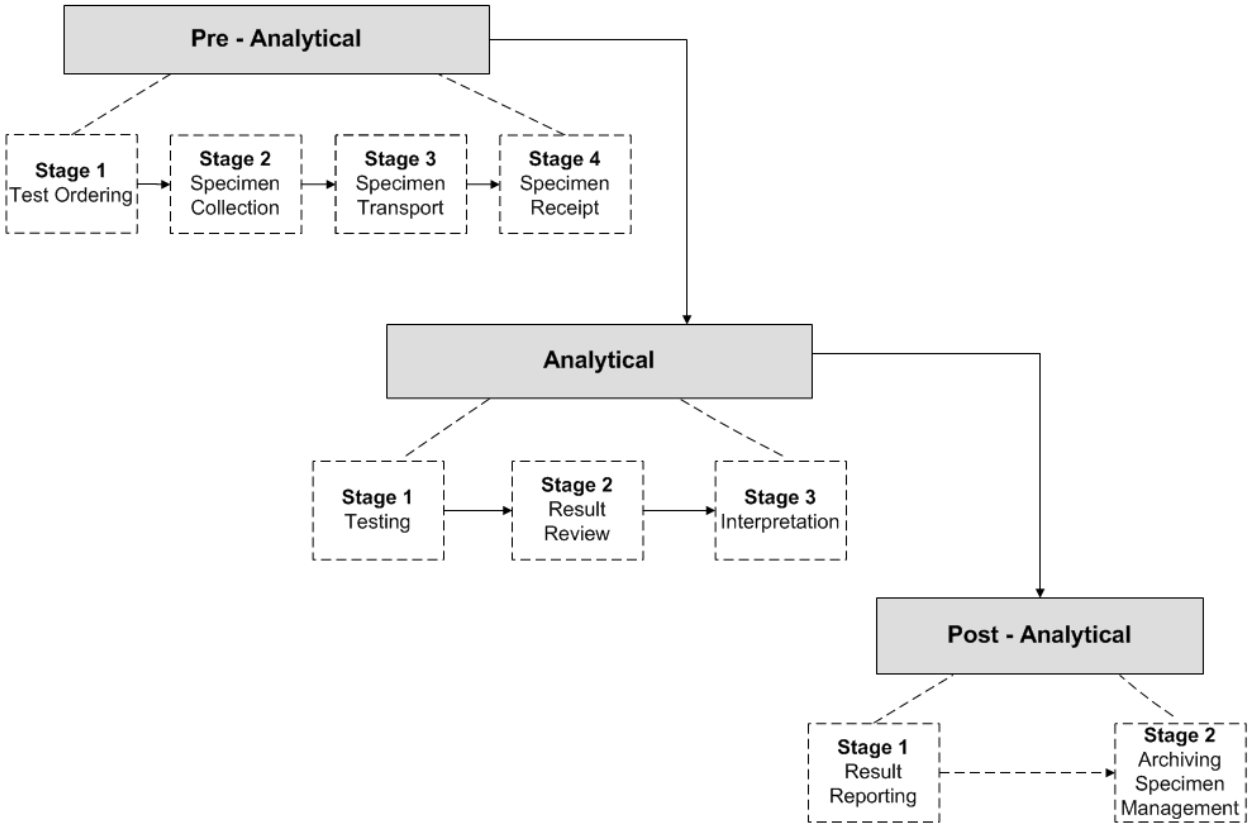
Many quality manuals are a compendium of individual procedures. They contain incredible detail about task-level work, but never really communicate the "big picture" of how the laboratory functions, and how procedures link together. By creating high-level diagrams for your major processes, you can develop a tool for making sure that all the elements necessary for quality are in place.

Mapping out processes requires time and effort, but it pays off by giving laboratory staff and management a clear picture of how work flows through the laboratory, who does what, and how processes can be improved.

Step back from your laboratory and think about how work flows through it. Identify how procedures fit together and contribute to process flows. One way to get started on this is to use the following table as a starting point.

Process	Sub Process
Pre-Analytical	Test Ordering
	Specimen Collection
	Specimen Transport
	Specimen Receipt
Analytical	Testing
	Result Review
	Interpretation
Post-Analytical	Result Reporting
	Archiving Specimen Management

You may want to use PowerPoint or Visio to create a visual map such as the following:

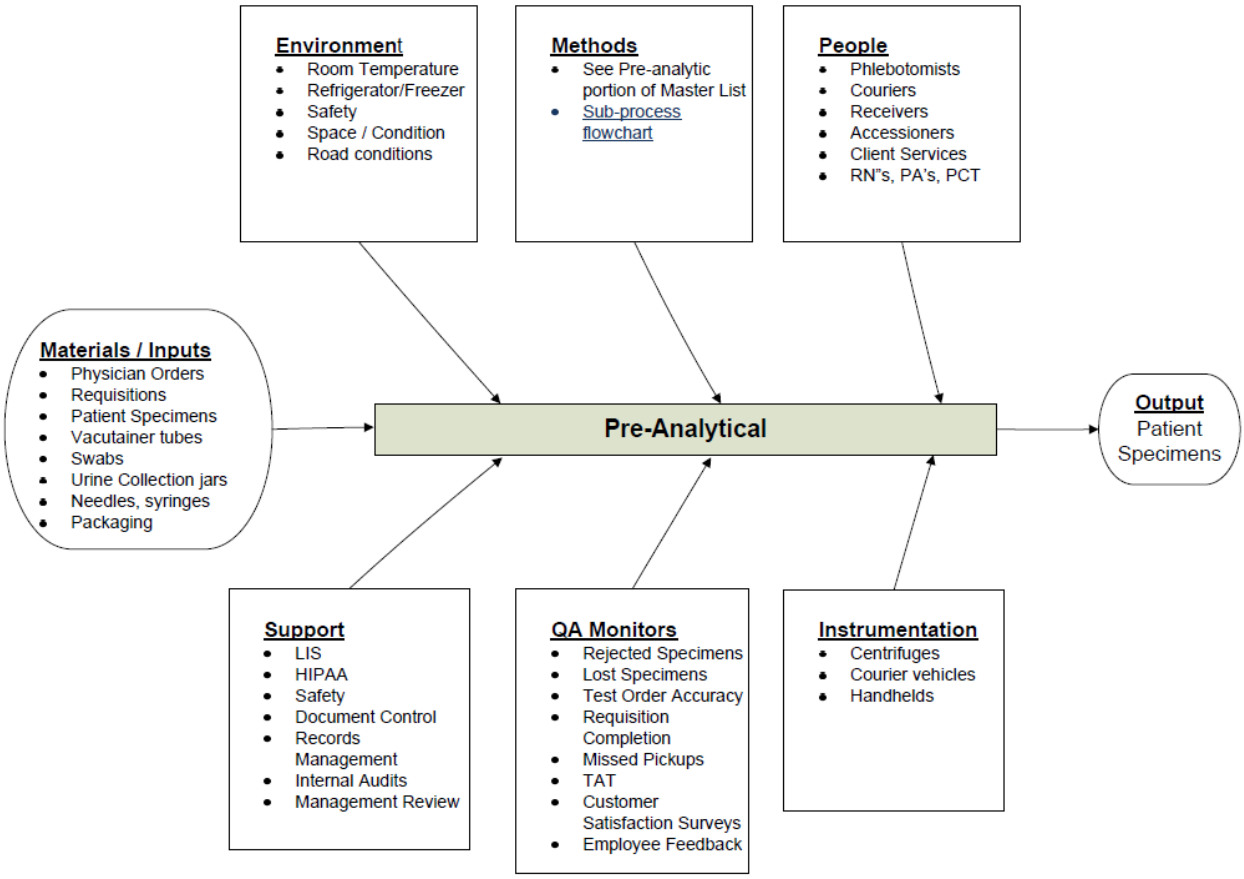


Core Processes and Sub-Processes (PDF)

Fishbone diagrams are another useful tool.

Quality teams often use fishbone diagrams in root cause analysis to identify problems. By prompting the user to consider all the things that contribute to the quality of a given process (methods, environment, people, instruments, metrics, etc.) fishbone diagrams help identify unexpected causes.

Consider using fishbone diagrams to show different aspects of processes.



Fishbone Diagram (PDF)

Note: For more information on developing fishbone diagrams, sometimes known as "cause and effect" diagrams, see the following site:

> Mind Tools Ltd. Cause and Effect Analysis: Identifying the likely causes of problems. Available at: http://www.mindtools.com/pages/article/newTMC_03.htm. Accessed July 11, 2011.

For the sub-processes, create tables. Show who does what and name the relevant procedures. Here is a table structure you can adapt with an example row from the Specimen Collection sub-process.

Step	What	Who	Related Documents
1	Generate labels	• Laboratory secretary • Phlebotomist • Technologist • Ward Clerk - ED	• PRE.349 Test Request and Ordering
2	Identify patient	• Phlebotomist • Technologist • Other appropriately-trained health care staff	• PRE.385 Patient and Specimen Identification • PRE.321 Becker-Maurer Laboratory Directory of Services • PRE.373 Specimens Requiring Chain-of-Custody

Your task is to make sure you understand how your processes link together and fit with your technical procedures.

3. Create your documentation

This QMS development step involves creating readable, user-friendly documentation of your processes and procedures. Documentation efforts that follow standardized methods are most successful -- for example, the Information Mapping standards and principles discussed previously under “Best Practices.” (infomap.com)

No doubt you have *many* policies and procedures to refer to in your quality manual, but they may not all be as user-friendly as you would like. You certainly would want to clarify the process maps and descriptions that will form the backbone of your quality manual. If there are procedures that are not yet ideal, you may want to create a prioritized list and improve the most critical procedures with Information Mapping techniques as soon as you can.

4. Assemble your quality manual

Finally, you are ready to assemble and summarize the elements you have developed so far into a single document that describes your quality system.

You will also need to include elements such as:

- Scope of laboratory
- Structure of documentation
- Organization chart
- Roles of manager-level personnel regarding quality

Consider the following Table of Contents from the process-based manual example as a starting point.

Topic	See Page
Quality Policy	
Quality Objectives and Metrics	
Scope of Services	
Structure of Documentation	
Key Processes and Supporting Procedures	
High-Level Processes Map	
Core Processes	
Fishbone diagrams of core processes	
Flowchart of core processes and sub-processes	
Tables of core sub-processes	
Support Processes	
Flowchart of support processes	
Tables of support processes	
Document Master List	
Laboratory Organization and Management	
Management Roles and Responsibilities	

Remember, the manual needs to contain the following sections:

1. The organization's quality policy, with corresponding quality objectives and metrics
2. Scope of laboratory services
3. Structure of documentation
4. Key processes and supporting procedures
5. A presentation of the organization and management structure of the laboratory
6. A description of roles and responsibilities of management with regard to quality

Note: For examples of these elements, see the "Quality Manual Example" tab. For tools to create your own, see the "Workplace Learning" tab.

Quality Manual Example

Click the link below to see an example of a quality manual that is developed using the approach described in this course.

Process-Based Quality Manual Example

Note: In this manual, for presentation purposes, analytical processes are limited to hematology, and sub-processes are limited to a single stage. Twp support process examples are included.

Here are some things to notice in this manual:

- The policy is clear and succinct.
- The metrics are critical, useful, and realistic to collect.
- The metrics are linked to the quality policy and objectives.
- The structure of the documentation is clear.
- The laboratory has done the work of understanding its processes and their interactions.
- The QMS and document control system are linked through the document references in the sub-process tables.
- The laboratory understands what influences quality in its processes (see fishbone diagrams).
- Both core and support processes are documented.
- Anyone who joins the laboratory can quickly understand who does what for a given process, and where to go for more detailed instructions.

Workplace Learning

Here are some tasks to help you apply the concepts in this course to your laboratory.

1. Find your laboratory's quality manual. Rate it according to the following dimensions:

Dimension	Rating (1-5, 5 is highest)
Provides a clear picture of how work flows through the laboratory	1 2 3 4 5
Clearly identifies key quality objectives and how they are measured	1 2 3 4 5
Easy to read and scan	1 2 3 4 5
Provides a tool for orienting new employees	1 2 3 4 5
Helps staff identify and locate key documents	1 2 3 4 5

2. Analyze the metrics that your laboratory is currently collecting. Are they linked to quality objectives? How useful is the information? Create and fill out a table such as the following.

Metric	Linked to quality objectives? Y/N	How useful? 1-5 (1 = little value, 5 = extremely valuable)
		1 2 3 4 5
		1 2 3 4 5
		1 2 3 4 5
		1 2 3 4 5
		1 2 3 4 5

3. Depending on what areas are strong or weak, consider revising and improving your quality manual. This might involve the following tasks.
    - Rewriting the quality policy
    - Linking elements of policy to quality objectives
    - Aligning metrics with the quality policy and quality objectives
    - Creating a diagram of the document structure
    - Mapping out and documenting processes

Follow the steps in the "Implementation/Plan for Development of Process-based Manual" tab to create your own process-based quality manual.

Here are some templates that you can use or adapt to create these elements:

- Quality Policy, Objectives, and Metrics Table
- High-Level Process Table
- Sub-Process Table

4. Draft a revision to the quality manual and discuss with your co-workers and quality manager.

Course Resources

Glossary

Term	Definition
Analytical	A process having the objective of determining the value or characteristic of a patient sample.
Audit	A systemic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.
CLIA	A law passed by the United States Congress in response to public health concerns over the largely unregulated laboratory services industry. Congress passed the CLIA - Clinical Laboratory Improvement Amendments (42 CFR 493) in 1988 to establish standards for laboratory testing and ensure the accuracy and reliability of patient test results. Facilities in the U.S. that perform laboratory testing of human specimens must comply with CLIA to obtain a certificate from the Department of Health and Human Services.
College of American Pathologists (CAP)	The leading organization of board-certified pathologists, which serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine.
Core Process	The processes that directly bear on the product or service that the customer purchases.
Corrective Action	An action to eliminate the cause of a detected problem or other undesirable situation.
Document	An information source and its supporting medium.
Document Master List	A list of all documents that are part of the laboratory's quality system, i.e., all policies, processes, procedures, work aids and other documents that support the core and support processes and are referred to in the quality manual.
Fishbone Diagram	A diagram that has the form of a fish skeleton that shows the inputs and outputs of a process, as well as the key factors that influence quality.
Information Mapping	A method for analyzing, organizing, and presenting content in a way that is clear and accessible. The method helps writers create documents that are easy to scan, understand, and maintain. For more information, go to www.infomap.com.
Infrastructure	The underlying foundation or basic framework of a system or organization; the resources (as personnel, buildings, or equipment) required for an activity.
Input	The state of activities and resources before a process is carried out.
Internal Audit	Sometimes called a first-party audit; an audit conducted by or on the behalf of the organization itself.

Term	Definition
International Organization for Standardization (ISO)	An organization based in Switzerland that develops and publishes standards for its international membership base.
Laboratory Accreditation Program (LAP)	An internationally recognized CAP program and the only one of its kind that utilizes teams of practicing laboratory professionals as inspectors. Designed to go well beyond regulatory compliance, the program helps laboratories achieve the highest standards of excellence to positively impact patient care. The program is based on rigorous accreditation standards that are translated into detailed and focused checklist requirements. The checklists, which provide a quality practice blueprint for laboratories to follow, are used by the inspection teams as a guide to assess the overall management and operation of the laboratory.
Management Review	A periodic review of the quality management system performed by upper management to analyze its effectiveness.
Metric	A measurement, or a thing that is measured.
Output	Activities and resources resulting from a process.
Policy	A documented statement of overall intentions, endorsed by management and chosen from among alternatives to guide and determine present and future decisions.
Post-Analytical	The process following the analytic procedures including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results, and storage of samples.
Pre-Analytical	The process preceding the analytic procedures from the clinician's request and including the test requisition, preparation of the patient, collection of the sample, and transportation to and within the laboratory.
Preventive Action	An action to eliminate the cause of a potential nonconformity or other undesirable potential situation.
Procedure	The specified way to carry out an activity or a process.
Process	A set of interrelated or interacting activities that transforms inputs into outputs. These activities occur over time with starts and stops and involve more than one person or group.
Process-based Quality Manual	A quality manual that is structured according to the core and support processes and sub-processes of the organization.
Quality	Meeting or exceeding customer and stakeholder needs and expectations.

Term	Definition
Quality Management System (QMS)	A set of interacting parts, functions, and activities designed to ensure quality in an organization's goods and services. It typically includes: • A well-planned set of processes for providing goods or services. • A system for monitoring those processes. • A system for improving those processes. • An infrastructure to support the systems and processes.
Quality Manager	The individual responsible for oversight of quality management activities, and who will champion the quality program and steer individuals in the organization to help with implementation and ongoing activities.
Quality Manual	A document specifying the quality management system of an organization.
Quality Objectives	Something sought, or aimed for, related to quality.
Root Cause Analysis	The process to identify the basic factor(s) that underlie variation in performance and then identify the most likely basic factor (root cause) of the variation.
Standard	A set of requirements. The ISO 15189 standard sets forth requirements for medical laboratories with regard to their quality management system.
Support Process	The processes that support the core processes.

Resources for Further Study

1. Information Mapping. Writing Plain Language eBook. https://www.informationmapping.com/en/shop/ebooks/writing-plain-language
2. Micklewright, Mike. Lean ISO 9001: Adding Spark to your ISO 9001 QMS and Sustainability to your Lean Efforts. Milwaukee, WI: Quality Press; 2010.

Self-check Quiz

1. A quality manual should contain which of the following?
    a. A description of the laboratory's quality management system
    b. Essential policies and management directives for bench staff to apply in testing
    c. Performance records for the laboratory's chosen quality metrics
    d. The laboratory's most important technical procedures

2. How does the quality manual benefit managers and supervisors?
    a. Enables management to prioritize preventive and corrective actions
    b. Explains how to perform root cause analysis to resolve quality problems
    c. Provides a centralized repository for all metric data
    d. Provides a tool for training new staff

3. Developing the quality manual is the responsibility of which person(s)?
    a. Internal auditors
    b. It depends on whether the relevant areas are pre-analytical, analytical, or post-analytical.
    c. Those closest to the actual work
    d. Top management, quality manager

4. When should a laboratory develop its quality manual?
    a. As soon as key processes have been established and documented
    b. At the outset of the quality management journey
    c. Concurrently with root cause analysis
    d. Concurrently with the internal audits

5. Which elements of the quality manual need to cascade logically from one to the next?
    a. Elements of quality policy, quality objectives, metrics
    b. Fishbone diagrams, sub-processes, metrics
    c. Overall laboratory metrics, manager metrics, supervisor metrics, staff metrics
    d. Pre-analytical, analytical, post-analytical

6. A quality manual should be structured around which elements?
    a. Activity menus
    b. CMS regulatory requirements
    c. ISO standard sections
    d. Processes of laboratory

7. What is a good way to make the quality manual more readable and scanable?
    a. Create a very clear topic sentence and summary sentence for each paragraph.
    b. Use Information Mapping techniques.
    c. Use the outline of the ISO 15189 standard.
    d. Use the outlining function in your word processing software.

8. Why are fishbone diagrams useful in a quality manual?
    a. They clarify who does what.
    b. They provide a way to streamline processes.
    c. They separate problems and causes.
    d. They show various influences on the quality of process outputs.

9. A quality management system contains which of the following elements?
    a. A basic checklist, a more detailed set of checklists for each area, a training system
    b. A management system, a testing system, a regulatory compliance system
    c. A set of well-planned processes, a way of monitoring processes, a way of improving processes
    d. A training system, a competency modeling system, an HR system for addressing cases where an individual simply cannot produce quality

10. How should the quality manual be written?
    a. As a checklist that will be used in actual laboratory procedures
    b. As a more detailed expansion of the ISO 15189 standard
    c. As simply as possible
    d. In the same way as regulatory standards

Answer Key

Question	Answer
1	a
2	d
3	d
4	a
5	a
6	d
7	b
8	d
9	c
10	c