CAP Quality Manual Development Course – Sample Content

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:

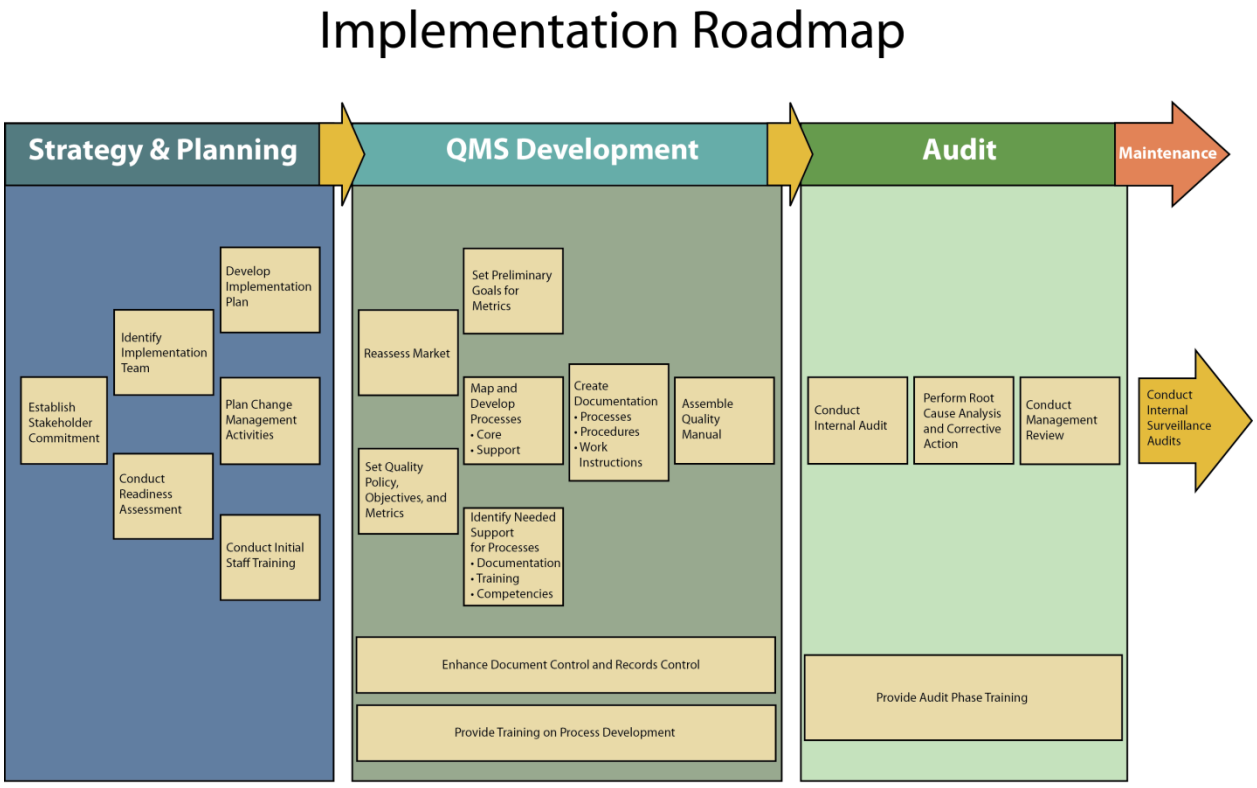
- Have access to the quality manual
- Have been instructed on the use and application of the quality manual and the referenced documents

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:

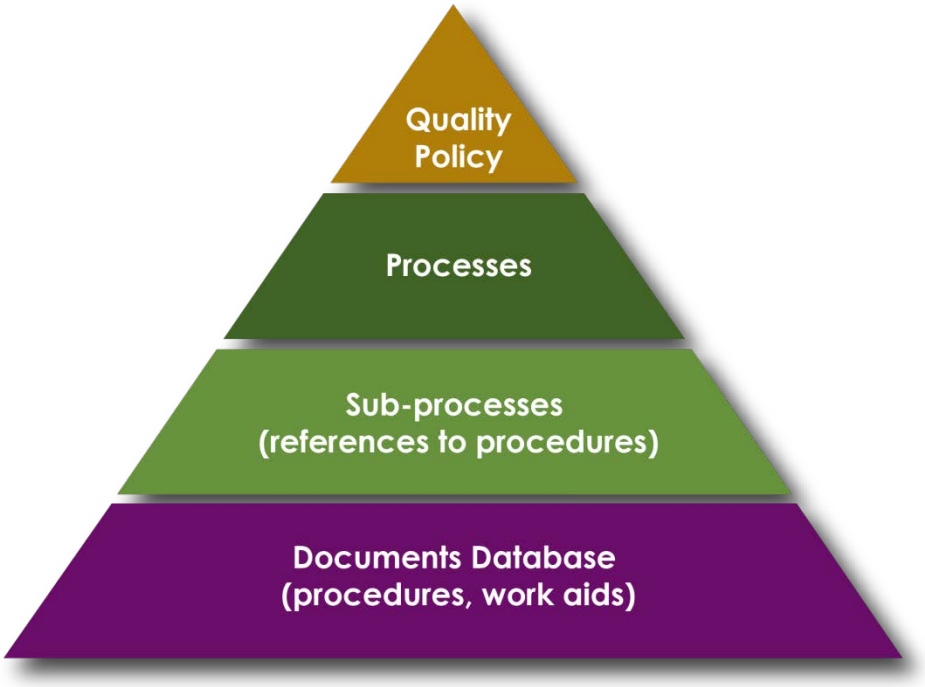
Disciplines
- Hematology
- Chemistry
- Transfusion services
- Microbiology
- Anatomic Pathology

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

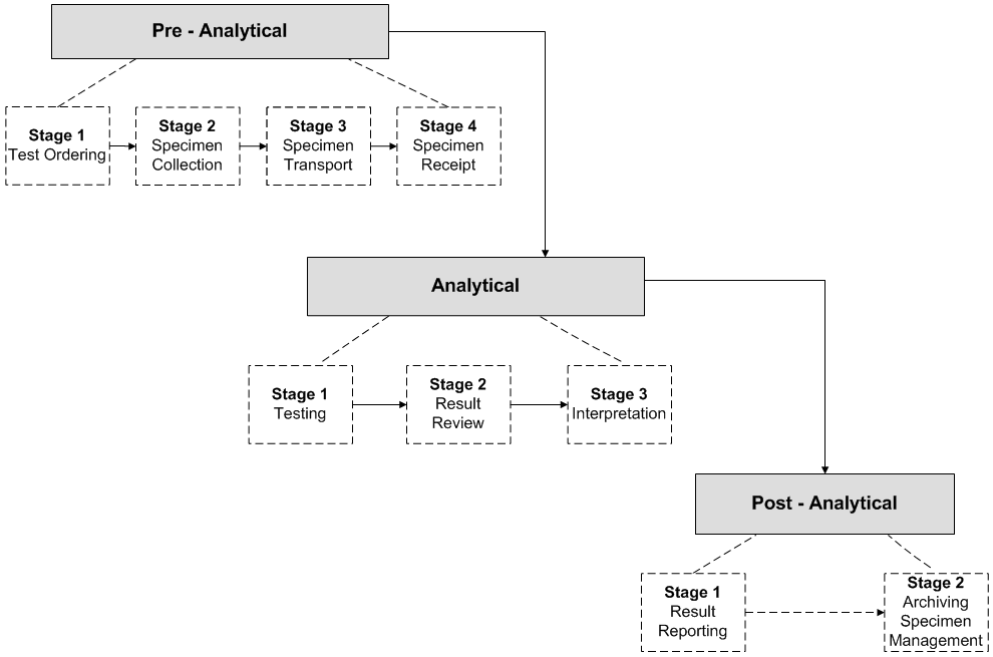
The ISO standard requires that the quality manual "include or make reference to" key processes and supporting procedures.

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.

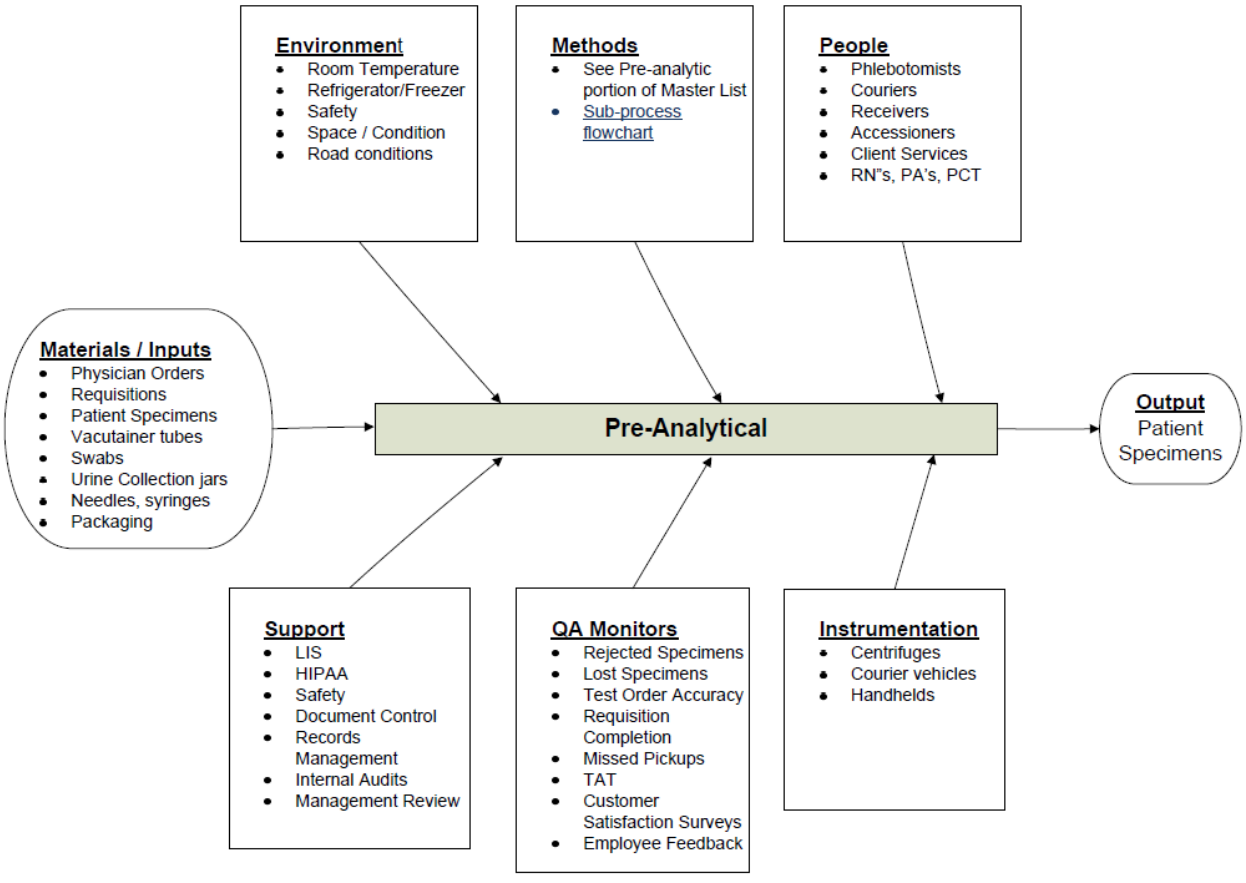


Core Processes and Sub-Processes (PDF)

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?

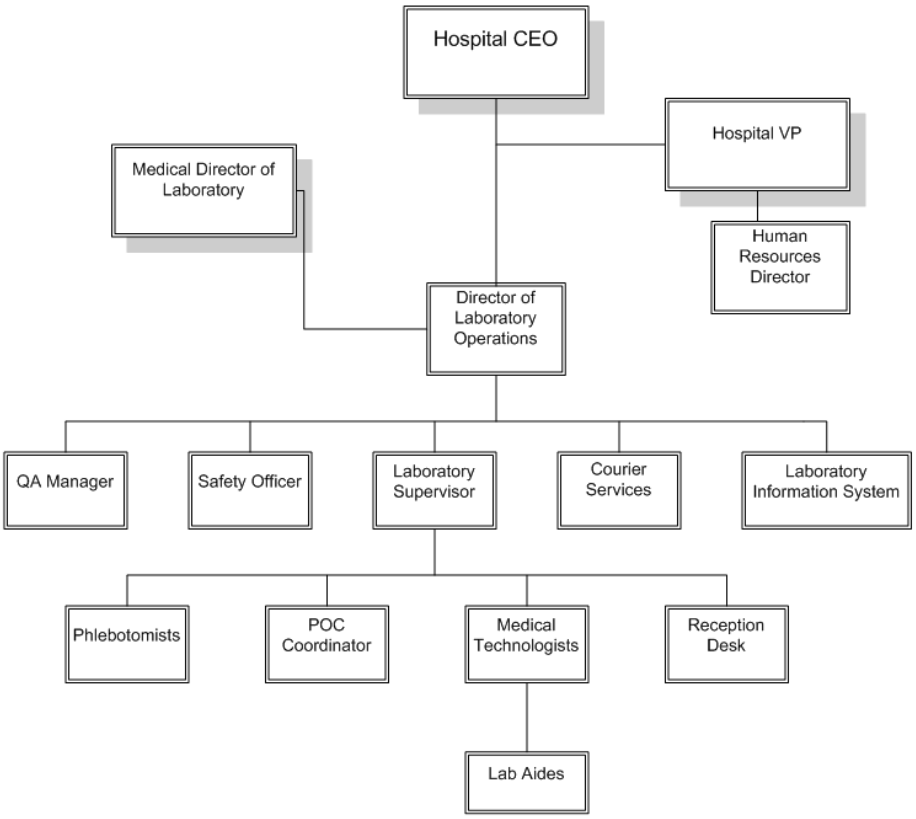
Once we understand the answers to these questions we have a basis for improving the handoff. We can store materials and information in a way that makes the handoff easy (for example, put material in freezer; put information in folder, send as email, or save a spreadsheet to a network folder).

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.

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 (Word)
- High-Level Process Table (Word)
- Sub-Process Table (Word)

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