Total Quality Management Series #4

Documents and Records

Introduction:

Documenting a quality management system involves the laboratory stating the quality policy (intent), and describing the quality system (implementation) in writing. The quality system is documented in quality policies, quality and operating processes, standard operating procedures (SOP’s), and records generated from performing procedures. The quality system is documented using a document hierarchy in a quality manual.

Various personnel in the laboratory document the quality system. Top management sets the quality policy. Quality function personnel, departmental managers and qualified writers document quality processes and develop operational processes and procedures. Employees create records by documenting actions and outcomes during the course of their day-to-day activities.

Approaches to Developing Documentation:

There are two (2) approaches to creating documentation. The first is to map processes and then to document policies. The second is to write policies first, identify the processes that support the policies and then map the processes. When documenting management activities in the quality manual, it is useful to draft the policies first using the quality system essentials and then identify processes that support the policy. When documenting the operational activities, it is useful to identify all the different processes, map the processes and then determine which procedures are needed.

Because many of the policies may cross departmental boundaries, it can be very beneficial to have representatives from the other departments that are involved in the process participate in sessions to draft documentation. For example, for Purchasing and Inventory it would be useful to have people from the purchasing department and the receiving department when you are creating the policy and process maps. This approach also allows the participants to really understand how the process works and reveals gaps when comparing with how the process is intended to work.

Everyone in the laboratory should be given the opportunity to provide input into the development of the documentation. The entire staff needs to be familiar with and understand the contents of any manual and its related documentation.

You will need to decide how you will implement the documentation before you start drafting manuals, policies and processes. Will you develop and issue all of the policies and processes as a completed manual? Or will you develop them one policy at a time with the supporting processes and then implement them one by one?
Issuing a complete manual will take a longer time but the finished product represents the entire picture. You will be able to hold training sessions for staff and highlight their responsibilities within the entire quality management system. However, you will need to delay auditing the system until everything is complete.

Issuing policies one by one will allow you to get your training, implementation and auditing started quickly. It may be easier for staff to understand and accept the changes if they are introduced one at a time. However, this method requires more training sessions for staff and could cause some confusion because there is no “Big Picture”.

**Quality Manual:**

The laboratory Quality manual is central to the implementation of an effective quality management system. The purpose of the Quality manual is to communicate information, share knowledge, and to provide evidence of compliance with requirements and of management’s commitment to quality.

The Quality manual forms the top level of the documentation hierarchy and describes the laboratory’s quality management system through a series of policies. There should be one Quality manual for a laboratory which applies to all departments. There will be one policy for each quality system essential. The manual may include processes, but does not usually include any procedures. It will usually refer to supporting documentation such as procedures (work instructions), records, forms and charts.

The format, structure and contents of the manual are at the discretion of each laboratory. It is convenient if the structure of the manual is based on the requirements or standards for which it is intended to comply. This makes it easier for both the user and the auditor to read the manual and find statements, which demonstrate compliance with requirements. The Total Quality Management Manual provides the additional documented policies and procedures required to implement an effective Quality Management System with the document name and/or number where this information can be found.

**Policy:**

A policy is a written statement of overall intentions and directions defined by those in the organization and endorsed by management. Policy documents describe “what we do and why” and are based on regulations, accreditation requirements and the laboratory’s requirements. There are three (3) types of policies required to document a quality management system – the quality policy, management policies and operations policies.

**Quality Policy:**

A Quality policy is a statement of intentions with regard to quality and is a requirement for a quality system under ISO 9001, ISO 15189 and the Ontario Laboratory Accreditation Program. This policy is kept in the Laboratory’s Quality manual.
Management Policies:

Management policies describe the laboratory’s management activities. There should be one policy for each Quality System Essential (QSE) or for clauses of ISO standards. These policies are kept in the Laboratory’s Quality manual.

Operations Policies:

Operations policy statements are put into process or SOP documents at the point the staff needs to know this information. These statements represent requirements of regulatory and accreditation agencies for technical operations. An example of an operational policy statement might be: “Alert values are to be called to the ordering physician as soon as possible after verification.” This could be included in the procedure for reporting results of a particular test.

Writing Policies:

When developing policies, consider what the audience, usually, management, assessors and new employees need to know. The audience might ask questions such as “What are we about?” or “Why do we do what we do?”. They should be able to find the answers to these questions in the policy. Policies define which processes are needed.

Process:

A process is one or more inter-related resources and/or activities that transform inputs (eg. intent, policies) into outputs (eg. instructions, procedures). It is a sequence of activities involving more than one person across a span of time. Process documents describe “how it happens here” and outline “who does what and when”.

Processes that go across departmental boundaries need to have the steps in the process not occurring in the laboratory documented. The laboratory still has a responsibility to document them even if they do not perform the activity.

There are two types of processes required to document a quality management system – management processes and operations processes.

- **Management Processes:**
  
  Each management policy requires one or more processes to be documented. QSE flowcharts or tables are part of the Quality manual.

- **Operations Processes:**
  
  The path of workflow, from test ordering to result reporting, needs to be documented. Operations flowcharts should be part of procedure manuals.
Writing Process Documents:

When developing processes, consider what the audience, usually, management, assessors, staff and process improvement teams need to know. The audience might ask questions such as “Who does what and when”? or “How does it happen here?”. They should be able to find the answers to these questions in the process document. Process descriptions may be in a flowchart or table format. Tools such as Visio, All Clear, Excel and Word can be used to prepare the flowcharts. Processes define which procedures are needed.

Procedures:

A procedure is a specified way to perform an activity. It provides specific instruction for performing a task and is usually performed by one person with defined start/stop times. It describes how the work is done.

One size does not fit all when it comes to writing procedures. There are several types of procedures that are required to document the quality management system. These include pre-analytical, analytical, post-analytical and computer procedures. Since there are different procedure types, there are different templates that can be used for developing these documents.

Writing Procedures:

When developing procedures consider what the audience, usually, assessors and staff need to know. Address the specific steps the individual is expected to perform. Use a layout that enables the user to perform the task correctly. Procedures are written in the active tense “[You will] action verb (write, call, type, etc.).

The procedure documents needed are identified from process flowcharts or tables. Each step of the process needs a procedure written to describe how to do the identified task. These are listed under the Supporting Document section in a process document.

Group procedures by work process and put the procedures in the manual in the order of the way they are performed in the work process. A procedure manual will have a table of contents, a process flowchart followed by each procedure in the order they are to be performed.

Documents required by the Quality Management System must be controlled.

Where applicable, controlled documents should include the following information:

- Title
- Reference number
- Date issued
- Date effective
- Revision level
- Review date or review frequency
- Revision history
- Author
- Approved by
- Distribution list
- Pagination and Computer file references
The organization’s system should provide a clear and precise control of procedures and responsibilities for approval, issue, distribution and administration of internal and external documentation, including the removal or identification of obsolete documents (to prevent misuse). This can be accomplished, for example, by making the documentation available on a central computer system, or by maintaining a master list of documents or data that records their level of approval, distribution (location of copies) and revision status.

Applicable documents must be accessible in the relevant places of work.

When retained, obsolete or superseded controlled documents should be clearly marked or kept in a secure location, and other copies should be disposed of. It may be possible to maintain detailed records of changes as they are made, rather than retaining actual copies of each issue of every document.

Where document control is achieved by electronic means, special attention should be given to methods for identifying appropriate approval of electronic copies, access, security, distribution, media, backup and archiving procedures.

Records:

There is no all inclusive list of specific records required of all facilities. However, laboratories must be able to provide evidence that its processes are effective in meeting the goals defined in their policies. It is up to the laboratory to define what records and documents are necessary to provide this evidence.

All records/requisitions, examination results, instrument printouts, etc. are to be stored so that they are readily retrievable. Facilities must provide a suitable environment to prevent damage, deterioration, loss or unauthorized access. It is the responsibility of laboratory management to determine its criteria for suitable storage conditions and to ensure that the criteria are met.

The laboratory must develop a policy that defines the length of time various records pertaining to the quality management system and examination results are retained. If time periods are not prescribed by legislation, the laboratory may consider retention periods by other means. In many cases, the statute of limitations provides guidance.

Summary:

Document and record control is essential for a successful quality management system. Documents provide direction and records produce evidence. Documents must be identifiable and obsolete documents removed from circulation. The laboratory determines what records it will keep, noting the OLA requirements refer to a number of records. All records must be stored for easy retrieval and retained for a defined time frame.