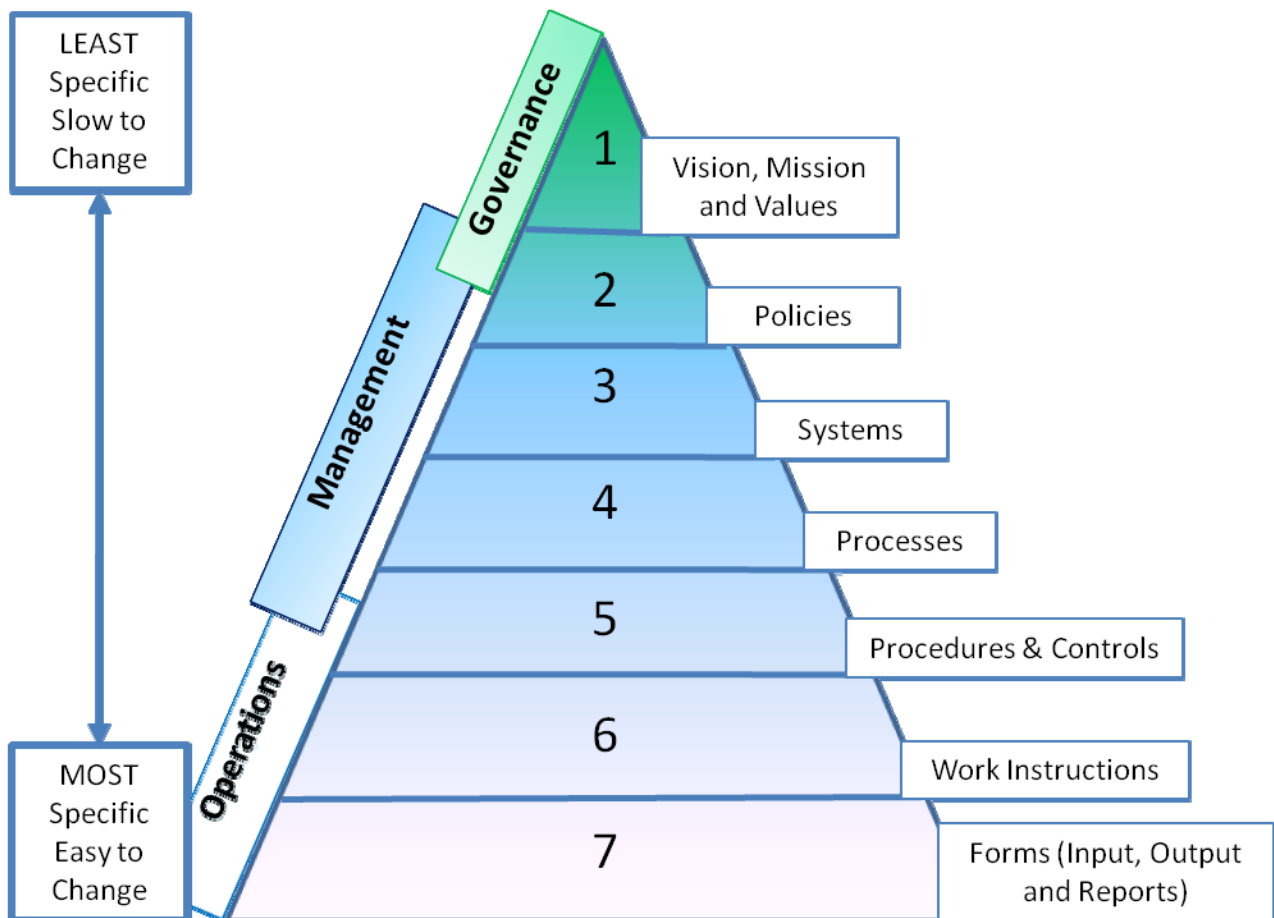


White Paper on the Road to Overcoming Overload



DOCUMENTATION STRUCTURE AND CONTROL RULES



Introduction

Organizational quality and operational empowerments require a reasonable level of structure, control and documentation. Proper documentation enhances communication and clarifies roles, responsibilities and accountability. Regretfully, whether it is in system development or organizational management documentation development and maintenance are often neglected. On the other extreme, risk aversion in some organizations, may lead to over documentation with negative consequences. In addition to information overload, this may lead to micro-management that hinders operational flexibility and empowerments. To ensure communication clarity of process and knowledge and decision making resources documentation must be updated and maintained regularly.

Leaders are encouraged to avoided complexity with its heavy overhead. This paper seeks to explain the purpose served by the various levels of documents and who is most likely responsible for creating them, approving them and maintaining them. This paper can be used to illustrate the level of empowerment, delegation or collaboration towards a more effective organizational life. The preceding diagram also illustrates which organizational entity holds the primary documentation responsibility as well as possible handover or overlap.

Documentation Levels ⁱ

The preceding diagram is a simplified explanation of the various levels of organizational documentation and controls. It borrows some concepts encouraged in the **ISO quality model**. It is important to note that in some cases more than one level can be combined in one document or category of documents. If this should happen, it is helpful to clearly identify each level and how it relates to and links to another. This is to avoid confusion of roles and to protect corporate integrity.

1. *Vision, Missions and Values*

This is the highest domain of governance to direct the welfare of an organization. **Vision statements** are a vivid, idealized description of a desired outcome of an organization, function or project. This should inspire, energize and help create mental pictures of the expected outcome. **Mission statements** are a clear and succinct representation of the enterprise's purpose for existence. It should incorporate meaningful and measurable criteria addressing concepts such as the moral/ethical position of the enterprise, public image, the target market, products/services, the geographic domain and expectations of growth and profitability. The mission statement should guide the consideration of stake holders evaluating strategic decisions. **Values statements** represent the core priorities in the organization's culture, including what drives members' priorities and how they truly act. Values are important not only in strategic planning but also in directing day to day activities.

2. *Policies*

Management policy level documents are general statements of the organization's commitment to establish systems and controls to fulfill its corporate mission and objectives. They reflect a commitment to meet requirements specified in applicable standards, guidelines, and regulatory demands. Policy level documents and statements often apply across the entire organization. These documents are normally initiated and approved by the most senior level in the organizational management. Policy level documents may have process level documents associated with them. The linkage and relationship between these two types of documents should always be clearly stated. **This should include monitoring and performance guidelines.**

3. *Systems*

Management systems documents seek to describe a group of interacting, interrelated, or interdependent elements forming a complex whole. In other words they highlight a functionally related group of elements, people, technologies, networks or even ideas. Systems are created and exist for the benefits and to serve the vision, mission, and value of an organization or a higher body. These relationships and their intended benefits should be described in the related documentation.

4. *Process*

Management and operational process level documents describe what is put in place to meet the requirements spelled out in the policies. These documents describe the process that relate to one or more systems, functions or departments in the organization. They also serve to highlight and clarify the level of empowerment and accountability for the various participants in the process or the function. Where appropriate, these documents serve as linkage to other processes. They may highlight the boundaries between one function and another.

Flowcharts and diagrams are very helpful in illustrating and explaining process level documents. They also serve to clarify the functional interrelationship. In addition, they can be used as a simplified functional or roles profile.

5. *Procedures and control*

Procedures and control documents seek to elaborate on the events in the process **and where needed** serve to describe in more detail:

- What is done
- Why it is done
- When it is done
- Who does it
- Where it is done and
- How generally it is done (without extensive “how to” details for each task)
- Reporting, **monitoring, and quality indicators should be included.**

These documents are normally initiated and approved by operational leaders in the organization these documents serve. These documents may have work instruction level documents associated with them where more the detailed “how to” is spelled out.

6. *Work Instruction*

Work Instruction level documents are the most specific “how to” instructions used by participants in the process to help them fulfill the assigned duties, tasks or work. These instructions are often quite detailed and can be used for training purposes.

Work instruction level documents are normally initiated and approved by the functional leaders in the organization these documents serve. These documents may have form level documents associated with them where more detailed input and output are spelled out.

7. *Forms*

Forms are support and communication tools. They are used to document the activities conducted in performing tasks or fulfilling a process. Once completed, forms become records useful in fulfilling regulatory requirements and progress measurements. Because of their importance forms at varying levels of control must be maintained by the organization for compliance and auditing and regulatory purposes.

General Rules for Document Control

The authorizing entity for any documents must clearly spell out appropriate document control procedures to ensure that all documents are approved, reviewed and updated as required. All copies in circulation must have the initials of the individual creating the document to verify their authenticity and legitimacy. Generally speaking:

You shall

- Uniquely identify all documents using a common numbering system
- Format all category documents in a consistent manner with consistent headings
- Ensure that all procedures are updated as changes occur
- Maintain a list of all controlled documents indicating current revision status and issue date
- Maintain one copy of all obsolete documents and destroy all other copies
- Implement a process to ensure that all new documents and document changes are approved by the necessary parties
- Maintain a record of all amendments to documents and clearly identify what was amended within the document
- Establish a system to document that staff is knowledgeable of the contents of procedure that relate to their functions
- Identify all documents by the document control system (policies, procedures, work instructions, forms, contracts, leases, standards and guidelines)
- Minimize the number of hard copies released of any controlled documents

You shall not

- Undertake the responsibility of initiating, creating or modifying any documentation for which you are not authorized
- Create procedures or make procedural amendments by memo or verbal instructions
- Retain copies of obsolete procedures
- Post controlled documents unless the document indicates (For Circulation)
- Implement new processes or amend existing processes until documentation of the process is available and appropriate training has been completed

ⁱ In addition to web based resources, a significant portion of this paper relies on training material provided by Ms. Darleen Henrickson, Quality Education Consultant, Medical Laboratory Technologists Association