

**The New Mentality of ISO Management Systems**  
Focus is now Adding Value

**Article 5 – Discussion of Clause 4 Topics**  
**February 2010**

**4.1 General requirements**

- **This is one of the key clauses of the entire standard because it sets the tone for any certified organization’s management system. It is quite clear that the driver of the organization’s system has to be based on establishing, controlling and improving its PROCESSES, not its documentation. The standard says that the organization must:**
  - **Establish, document, implement, maintain and continually improve the effectiveness of its system.**
  - **Determine its PROCESSES.**
  - **Determine the sequence and interaction of these PROCESSES**
  - **Determine criteria to ensure these PROCESSES are effective**
  - **Ensure the availability of resources to support and monitor these PROCESSES**
  - **Monitor, measure and analyze these PROCESSES**
  - **Implement actions to achieve planned results and continually improve these PROCESSES**
  - **Ensure control of outsourced PROCESSES.**

**4.2 Documentation requirements**

- **4.2.1 lists the documents that are required for the organization’s management system. (Please make sure they meet the requirements of 4.2.3). I will talk about a few of them individually below. However, the NOTES in the standard are important because they are clear indicators of major paradigm shifts from ISO 9001/2/3:1994.**
  - **NOTE 2 states that the extent of documentation can differ due to the size of the organization and type of activities, the complexity of its processes and the competencies of personnel. Simple processes and highly skilled employees with documented competency levels typically do not need as much instructional documentation (work instructions) to perform their assigned tasks. Do not put procedures or work instructions in place just to have them. Meet the four sources of requirements yes, but do it in a way to add value to the PROCESS it describes.**
  - **NOTE 3 clearly states that documentation can be in any form or medium. This is very powerful when we really think of what is being said. The old school thinking was to have multiple layers of internal requirements – procedures / work instructions / records. The question <Why?> begs to be asked. When we think about it, one document can fulfill the requirements of all three. (Don’t forget that the new definition of a procedure in ISO 9000:2005, 3.4.5 is “a specified way to**

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carry out an activity or a process”). Who specifies the way? The organization. Think about the receiving process. Most organizations (service as well as manufacturing) today have someone designated to receive the material ordered, check it against the Packing List and/or Bill of Lading, then go to a computer to pull up the Purchase Order (PO) or some other type specification. The receiver then fills in the quantity and part number, etc. required by the data base or excel spreadsheet, hits “enter” and the information automatically updates the organization’s inventory system, and notifies Purchasing that the item has arrived. Guess what – training on proper use of the computer and software package becomes the procedure, the database or specification is the plan and serves the purpose of the work instruction and the data entered becomes the record. Normally, you don’t need a lot of additional “stuff” to perform that particular activity. If something needs to be changed to make the receiving process more effective change it on the software package being used, not on layer after layer of “instructions.” Process control and effectiveness should be the driver, not layers of paper that create many opportunities for the organization to shoot themselves in the foot with errors.

- **4.2.2 Quality manual.** Adhering to the wording of the standard here absolutely presents the best way for an organization to develop this high level document. The quality manual sets the tone for the entire system to either have it focus on its PROCESSES (as intended by the standard), or to have it focus on its documents and completely miss the boat of using the system to manage the business. It is surprising how many organizations write their quality manual to regurgitate the standard. My question is: If you want to know what the standard says, where is the best place to go? Obviously, to the standard itself. Write your quality manual to meet the requirements stated in 4.2.2. When it is done this way you will force the entire system to focus on the requirements stated in 4.1, and this is when your organization gets the bang for the buck. And – guess what – your 25-40 page manual will now become 1-3 pages that forces your organization to focus on your PROCESSES, not your documentation.
- **4.2.3 Control of documents and 4.2.4 Control of records.** These are two of the six required documented procedures. (Some organizations choose to combine these into one procedure). Please do not just repeat the words of the standard. As the third party auditor I know what the standard says. I want to know how your organization chooses to meet the required controls. Again, make these PROCESS descriptions add value to your organization.

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