

## **The New Mentality of ISO Management Systems**

Focus is now Adding Value

### **Article 4 - Documentation**

**October 2009**

**During the revision process for ISO 9001:2000, TC 176 recognized that no organization operates based on documentation – they operate based on processes. Consequently, the TC wisely reduced the number of required documented procedures from 30 to six with ISO 9001:2000, and it has stayed the same with ISO 9001:2008. We now recognize that how an organization chooses to document something has to be their responsibility, and theirs alone. As auditors, our job is to ensure that the system contains the required documents (see 4.2.1), yes, but we have to go much farther to make sure that it is effective. Are the processes working to give the organization the bang for the buck they should be getting?!**

**ISO 9000:2005, Fundamentals and Vocabulary, 2.7.1 specifically states: “Generation of documentation should not be an end in itself but should be a value-adding activity.” We used to want to see all four levels of documents (Quality Manual, Procedures, Work Instructions (as they were called then) and Records), but no more. One well constructed document can easily satisfy the requirements of three of the four levels of documents just listed. Start with the six required procedures, and then add documented procedures only when they can be soundly justified. You must document your system, but how you document it is your call. It is suggested that you use all resources available to you to create your documents: flow charts, checklists, databases, spreadsheets, etc., etc. Just make them meaningful, have them add value to the organization and control them.**

**One thing – never, never create a document because you think an auditor will want it, or because you think it is needed just to pass an audit. Do it because it makes good business sense. Just make sure the requirements of the standard are being met.**

**Also, don’t forget that documents can be any form or medium. A well constructed software program can easily provide the plan as well as the record of activities for almost all processes. This will become apparent as we move forward.**

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