

ISO 9000 is not Rocket Science

Dispelling the “Myths” of ISO 9000

Part Two of Four

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Plan

Some companies have over documented their management systems to the point where they are useless based on their misperceptions or lack of understanding of the ISO 9001 standard. Nowhere in the ISO 9001 standard does it say how a company is required to do a process; it simply tells them that they need to meet a requirement (generally the customer requirements). It is the company's prerogative on how they define their processes and how they meet their requirements. This is extremely important and the main reason why companies often struggle and fail to create a cost reducing, effective ISO 9001 program. Many companies when trying to implement an ISO 9001 program define their program based on what they think the standard implies or what an auditor may expect to see. If not for ISO 9001 requirements, most companies would never implement something they did not need to succeed in business. However, when it comes to implementing an ISO 9001 system companies define many of the programs based on perception and not on the company's actual processes or culture.

- Perception: My Quality Manual has to plagiarize the ISO 9001 standard
 - **False:** the ISO 9001 standard states “The organization shall establish and maintain a quality manual that includes:
 - The scope of the quality management system, including details of and justification for any exclusions,
 - The documented procedures established for the quality management system, or reference to them, and
 - A description of the interaction between the processes of the quality management system.”
- Perception: I must have a document (work instruction, flow chart, procedure, etc.) for every process in my company
 - **False:** the ISO 9001 standard states “NOTE 2 the extent of the quality management system documentation can differ from one organization to another due to the size of organization and type of activities, the complexity of processes and their interactions, and the competence of personnel.”
- Perception: I must have a matrix that lists my processes and references all of the sections of the standard that apply to these processes
 - **False:** the ISO 9001 standard states “4.2.2 quality manual; The organization shall establish and maintain a quality manual that includes a description of the interaction between the processes of the quality management system, and determine the sequence

and interaction of these processes. NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization and measurement, analysis and improvement.

- Perception: I have to have form numbers and revision or date control on all of my forms
 - **False:** the ISO 9001 standard states “Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.” Nowhere in the standard does it even talk about forms or controlling forms.
- Perception: We have to have a master list of documents or a master list of records that tells me where they are stored, how long they are kept, etc.
 - **False:** the ISO 9001 standard states, “Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention, and disposition of records. Records shall remain legible, readily identifiable, and retrievable.” Nowhere in the standard does it talk about master lists.

Documenting your management system

The first step in implementing an ISO 9001 system is to document your management system. The required documentation is a Quality Manual that could be named a Business Systems Manual because it covers the scope of your entire business, not just the quality aspects. There are also six required procedures (control of documents, control of records, internal audits, and control of nonconforming product, corrective action, and preventive action). The company may define any additional documentation.

The Business Systems Manual: there are three requirements to be included in your manual.

1. A scope which includes any exclusions you may have,
2. The procedures or reference to the procedures for your management system and
3. A complete description of the interaction between the various processes that are required to operate your business.

These are the only requirements of a Manual. Yet so many companies write 30 to 60 page manuals that have so much detail in them and often refer to outdated processes or requirements. When written correctly, the Manual could be a perfect marketing tool to send to customers that simply tells them the scope of their management system and provides a picture of the interrelation of their processes. The interrelation of processes can be as simple as an overall picture of how your company’s processes flow, and needs to incorporate your control of production/service (planning, measuring and monitoring) and your continual improvement processes (control of nonconforming, corrective and preventive action, internal audits, analysis of data and management review).

The six required procedures that need to be written are:

1. How the company controls their documents,
2. How the company controls their records,
3. How they process nonconforming product,
4. How they conduct and record internal audits,
5. How they process corrective actions and
6. How they process preventive actions.

The standard does not tell you how to do any of these processes; it simply provides guidelines and tells you that you have to document how you perform these processes. If you get nothing else from this article, please pay attention to this area – do not document your processes or required procedures based on what you think the standard implies or what you think the auditor is looking for. You must document your management system based on how you conduct your business!

Any other work instructions, flow charts or procedures that you feel your company needs to effectively produce the given product or service, should be done in a format that best suits the purpose controlling these processes. The most important part of documenting any type of process (management process or product process) is to define the inputs, outputs, and measurements of the process. The better your company defines how to measure each process, the easier it will be to monitor the outputs (data) and pin point the areas that require improvement.

The level of complexity or volume of a documented management system has nothing to do with the size or complexity of the processes of a company. The only direct relationship you would find as to what level of documents a company requires would be the effectiveness of their training programs. The more effective the training programs are the fewer documents you would expect to see. For example, you may need a work instruction to teach someone how to do something (training guideline/reference document), but once the person or people are trained, there is no more requirement for that document.

A colleague, Mr. Peter Sanderson from TQMS Inc. explains this approach clearly and he calls it the bow tie approach to quality management. Below is his explanation:

“In 1995, I was invited to a white tie event and purchased a tuxedo. They asked if I wanted a clip on bow tie or a real bow tie. Since I wear a real tie every day, I purchased the real bow tie. Well, it came with the standard printed instructions on how to tie it. When I arrived home, I could not follow the directions or learn how to tie the bow tie. The next day, I took it to my office and had all of my consultants work on learning how to tie the bow tie. They tried on doorknobs and on each other with no success. Later that night, my 7-year old daughter put the bow tie around her ankle and tied a bow. She slipped it off her foot and handed it to me and asked; is this a bow tie? To my surprise, it was a genuine bow tie. She told me that they should call it Tie-A-Bow rather than a bow tie. She said it was the same as tying your shoelaces. Therefore, I closed my eyes, wrapped the bow tie around my neck, and tied a bow like a shoelace. There it was, that simple!

Later that evening, I realized that as consultants, we do the same thing. We create hundreds of procedures and work instructions to help the owners sleep better at night thinking that they have everything under control. The reality of course, is that new people coming in to learn simply cannot learn by reading the procedures. I would demonstrate this at seminars by handing a volunteer the instructions and a bow tie and not once, did anyone figure out how to tie the bow tie. So I asked how much did it cost

to create the bow tie procedure, how much will it cost in the future to maintain the procedure and how effective was the procedure? The answer was that the procedure did not help at all. Training was the key. Once I would tell the volunteer the trick and that it was the same as tying his shoelaces, they would have no problem. Then once they learned, they had no use for the procedure. I suggested that if there were the instance whereby a salesperson must wear a theme bow tie that would be different for each customer they visit; then a simple spreadsheet listing the customers and the required theme bow tie would be sufficient providing the sales personnel were trained on how to tie a bow tie.

As you can see above, a simple task was turned into a nightmare by some consultant long ago who wrote this bow tie procedure, which is now a standard and handed to all people who buy a bowtie and would like to know how to tie it. To view this procedure, simply search on a search engine using the phrase: "how to tie a bow tie".

The **common sense approach** to documenting your management system:

There are many requirements in the standard that say you must "define" a process. Define a process does not mean the same thing as document a process; you can define it verbally, with pictures, in a video or in a document. For example, if you have a process and you are deciding if you need a procedure, flow chart, work instruction, etc. to "define" it, ask the following questions and document your management system according to the answers.

- 1) In order to perform this process consistently and correctly we need a step by step instructions to be used by the operator while performing the process – if the answer is yes then document the steps of the process to be used by the operator;
- 2) In order to train employees on this process I need step by step instructions – if the answer is yes you can document the process as an instruction or you can document the process as a training or guideline document and use it only for training new people and not for conducting the process. Consider training videos in this instance;
- 3) It is a required document (one of the six required by ISO 9001, a customer requirement, a regulatory requirement) – if yes then document the process;
- 4) The last auditor said we need to document this process – this is not a valid reason to document a process.

Do not document your management system for the sake of documenting your management system. If you write a document that nobody ever looks at or uses, and it is collecting dust on a shelf or taking up space on your computer, then get rid of it. The reason to document a process of any kind is so there is a clear understanding of the roles, responsibilities, tasks, inputs, outputs and most importantly measurable criteria of the process.

For example, if a company says that all their forms will have a form number and revision on them, then all their forms must have this. The standard does require forms to be controlled or to have a number or revision. This would be an example of a company adding a requirement beyond the requirements of the ISO 9001 standard. Requirements should only be added when it will benefit your company by ensuring better processes. Do not add this type of requirements based on a perception of the standard or advice given to you by an outside party including an auditor.

The following example highlights the disadvantages of over documenting your management system:

- Your documented management system should help you process more efficiently versus tie you down to unrealistic requirements. Example, a small machine shop manufactures less than 20 parts on a regular basis. They have very detailed instructions that call out every requirement needed to make the parts. Their processes are very clear and very efficient. They make quality parts and deliver them on time. They hire a consultant to help them implement a management system. The consultant gives them a set of templates and puts their company name in them. The quality manual is more than 60 pages, the purchasing procedure is more than 30 pages, there are more than 50 forms called out in the new procedures all with form numbers and revision control. Although the company has great processes, reviews customer requirements, produces to customer requirements and implements preventive actions they do not even come close to meeting the requirements of their new documented management system. The important lesson here is that the company is responsible for understanding the ISO 9001 standard and understanding how they should define and document their management system so that it will match what they actually do.

The remainder of the article is broken out into two additional parts where we will identify the relevant *myths* in each:

3. Do and Check;
4. Act and Summary