

ISO 9000 is not Rocket Science

Dispelling the “Myths” of ISO 9000

Part Three of Four

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Do

Once you have defined and documented your management system, you now carry out these processes according to the *plan*. These processes include your production or service processes, supplier management, purchasing, receiving, calibration, etc. Depending on what your organization does, some of these processes may be excluded from your management system. When you define the scope of your management system, you are able to exclude portions of Section 7 of the ISO 9001 standard that does not apply to you.

- Perception: I have to rate my suppliers and have reevaluation records of all of my suppliers
 - **False:** the ISO 9001 standard states, “The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization’s requirements. Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.” Again, the company defines how they evaluate suppliers and depending on their needs, some may be more formal than others may.
- Perception: Every piece of measuring equipment has to be calibrated, or if not it requires a reference only sticker
 - **False:** the standard does not talk about calibration stickers and does not require reference only stickers.

Actually, producing parts or performing service according to a plan (traveler, router, instruction sheet and so on) is usually the strength of a company. Meeting the requirements of this part of the standard is straightforward.

Check

There are many methods to verify your processes and management systems. You may check your production and service processes by inspection or verification. You may also check your processes and management system by conducting internal audits. Another check or verification that is at your disposal may be third party audits performed by a consultant or registrar and customer audits.

- Perception: I need internal audit forms and to issue observations, minors and majors from my internal audits
 - **False:** the ISO 9001 standard states, “The audit criteria, scope, frequency, and methods shall be defined (by the company). Records of the audits and their results shall be maintained”
- Perception: I have to audit all of my processes (or my personal favorite: “*all elements of the ISO 9001 standard*”) at least once a year:
 - **False:** the ISO 9001 standard states, “An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits.” This means the company defines how many audits they do, how often they do them and what processes they audit (no requirement to audit all elements of the standard in any period).
- Perception: Management Review has to be done in a meeting and all of the inputs and outputs of 5.6.2 and 5.6.3 of the standard have to be on the agenda
 - **False:** the ISO 9001 standard states, “Top management shall review the organization’s quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained.”

Third party auditors are there to perform an audit to measure conformance to the company’s documented management system and to the requirements of the ISO 9001 standard. It does not matter if they agree or disagree with how a company decides to document their management system, control their documents, conduct their management reviews, conduct their audits, or measure customer satisfaction. The bottom line is that if the company says they do something in a certain way, they do it that way, and it meets the requirement of the standard, they are in conformance with the requirement.

Third party ISO 9001 auditors (registrars) need to be very careful what they say or do in an audit. They are not permitted by the RAB/QSA to consult during an audit. Consulting must be left to consultants. This is a very good rule. As an ISO 9001 registrar auditor, they are at the company one or two days, maybe a week at most. They are there to verify if the company “does what they say, say what they do, and meet the requirements of the standard”. The auditor is not there to tell the company how they should or should not do something. If an auditor is going to write a nonconformance to the company, the nonconformance must be against a requirement in the standard that was not satisfied or a requirement that the company put upon themselves in one of their documented procedures that was not satisfied. A major portion of nonconformances written to companies is against the company’s documented procedures. The following are reasons that this situation exists:

- The company documented their processes beyond the requirements of the standard. This happens when the company does not first think through the actual requirements and processes that they need.

- There is a lack of employee and management understanding and participation.

Another common issue is how a company's internal audit procedure says that they will audit every element of the standard at least once a year, or that they will respond to a corrective action request in 24 hours and so on. Again, it goes back to documenting your management system based on a common sense approach. Do not document a process based on what you want it to be or what you hope will happen! Document a process based on why you are performing the process and what do you want to get out of the process. Let us take the internal audit procedure above for an example. The first question the company should ask is why we want to conduct internal audits. There should be many answers, such as it is a requirement of the standard, but, more importantly, it should be because you want to measure the performance and effectiveness of your processes and identify opportunities for improvement. Nowhere in the standard does it say that full systems audits must be performed once a year or using an internal audit form, or on a set schedule planned a year in advance. It simply says, "An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits." Again, the company decides how to do this. It should not be based on what they think the auditor wants to see; it should be based on how they will get the most out of it. Example, the company may decide that after they review trends of data and decide what areas need improvement that they will schedule an audit of that area or process, review the processes using the "why", and "what if" approach to try to discover areas for improvement that may eliminate these trends. Upon completion, the internal auditors shall review this with management to make a decision (assign actions) to correct the trends and improve the process.

Audits and Analysis of Data

How you audit your management system and analyze the data that comes out of your management system will directly relate to how much money you save your company by using your ISO 9001 system. If you want the most from your internal audit system, you must go above and beyond checking to see if you "do what you say, say what you do". You need to ask questions like

- "How do you measure the effectiveness of this process?"
- "When you don't get the desired result, what do you do?"
- "Why do you do it this way?"
- "How do other departments affect this process?"
- "What do you think could improve this process?"
- "What are some preventive actions you can think of or that you have implemented for this process to prevent a potential problem?"

The answers to these questions are what management will review and decide if they need, or should take action to improve the process. The management team does not really care that you have pages of filled out checklists in a book that says the processes match the procedures and that there were no findings. If the management team is going to invest time and resource into

the auditing activity, they want to have information brought to them of how they can improve their processes and ultimately become a better company.

Analysis of data is also extremely important. Data (outputs of your processes) should be analyzed by cost and occurrence. The driving force behind implementation of an ISO 9001 system is the collection of data and methodical approach to reviewing and analyzing the data to identify areas where you can save money or improve your processes. Again, management review and analysis of data is not so you can have a meeting, spend days creating fancy reports and graphs so you have a record for the ISO auditor. The reason you review and analyze data and performance of your management system is to identify opportunities, take action, and follow up to see that these actions were effective.

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

4. Act and Summary