

# ISO 9000 is not Rocket Science

## *Dispelling the “Myths” of ISO 9000*

### **Part Four of Four**

By Bretta Kelly, President CIS WWSG

#### **Act**

##### **Assigning Actions**

There are so many places in an ISO 9001 system where you may assign actions. Coming up with the best method to assign, communicate and follow through on actions is the basis of continual improvement.

- Perception: I have to send out customer surveys to my customers to measure customer satisfaction
  - **False:** the ISO 9001 standard states, “As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined” (by the company).

Unfortunately, companies often struggle with how to do this. There are companies who assign actions from internal audits on an internal audit form, customer complaints in a log, nonconformity reports on another form in another log, actions from a management review in the minutes, actions from a production meeting in a spreadsheet, action to their vendors on another form and so on. Many times there are so many actions open, past due, pushed out or not communicated, that they have no way of knowing if their actions are effective or not. Sometimes, they may have a corrective action system that reminds them when an action is due, but there is no follow up for effectiveness. Other times actions are assigned in meeting minutes, and if the next meeting is not until the next quarter or the next year, they have no way to know if the action was taken or not, let alone, if it was effective or not.

If you don't know what result you want from an action, who is going to execute the action, when you want it completed by, and how you are going to measure if the action was successful or not, then why bother assigning it?

#### **The difference between closing an action and verifying if an action is effective**

There is a huge difference between closing an action and verifying if an action is effective. For example, a company may have an action list in an excel spreadsheet where they assign actions from various meetings. The spreadsheet includes the problem statement, required action, who is responsible, when it is due and a closed (yes/no) column. In a meeting, Managers go around the

table and ask if the action was taken or not, and if so, it can be closed. Who should care if it is closed or not? Should we not care about the action's effectiveness? Let us say you found a problem and the action was to do some training or add a new fixture. When the training is completed, or the new fixture is implemented, you generally close the action and put it in the closed sheet of the spreadsheet. Would it not be more important to see if the training or the new fixture actually solved the problem? If it did, then we have accomplished our objective towards improvement. We have in fact, prevented the problem from recurring. If you are still issuing nonconformities for the same problem, then additional action needs to be taken.

Again, do not assign actions for the sake of assigning actions. If you are going to assign an action, follow it through to ensure it is effective.

### **Defending your ISO 9001 system**

This is a true story to illustrate why you should not make changes to your ISO 9001 system based only on external advice:

A Management Representative of an ISO 9001 system inherits a management system that consists of more than 600 procedures and work instructions. An external auditor required them to add many new requirements to their Quality Manual (which was already more than 40 pages long and at revision J or K at that time). They were also instructed to create an audit schedule that resembled an audit report form that was more familiar to the auditor. Six months later, a new auditor arrived and the management representative was instructed to add even more specific requirements to the Quality Manual and more non-value added items to their already over revised management system. When the third auditor arrived six months later, they were advised to change their management system back to where it was the year before.

Clearly, something was wrong! The management representative went to a Lead Auditor Course to try to understand ISO 9001 and exactly what is required from the documentation. It is not surprising that they discovered that the ISO auditor had no business telling them how to document their management system.

It is very difficult not to be intimidated by an auditor. Executive management is habitually focused on becoming ISO 9001 certified (certificate for sales) and unfortunately, management's perception to this prerequisite is to comply with the auditor's requirements, since this will obviously "fast-track" the certification process. Frequently the company knows that they are right (common sense), but will choose compliance to the auditor's requirements over confrontation. This choice performed year after year is the foremost reason that the company's management system becomes less recognizable to their actual processes over time. It is also the cause of employee dissatisfaction with ISO 9001 and their lack of participation.

Therefore, the only occasion a company should have to update a procedure, or add steps to a process, is when the company decides that it needs to be done based on their analysis of the process and how to improve it.

Most auditors are looking for conformance to a standard when they are auditing. If they do find nonconformance, they generally are diligent in making sure it is valid and aligned with the standard or the company's specific documented procedure. The only defense a company has against an auditor that may be giving bad advice (or unknowingly writing invalid nonconformities) is to understand the standard and your own documented management system to the point where you know the difference.

Remember that the role of an ISO 9001 registrar auditor is to measure conformance of the company's management system and they are not permitted to perform consulting. When they do write a nonconformance against a management system, it must be against the standard or the company's specific documented management system. If the nonconformance does not point to a requirement in the standard or the company's specific documented management system, then the company should question it and only change their management system based on their analysis of their processes and the ISO 9001 standard with consideration given to improvement. This is not to imply that a company should be defensive or fight every nonconformance. Certification to the ISO 9001 standard is a process and the registration audit is just one small part. In summary, the best defense is education and understanding of the ISO 9001 standard and its requirements for your specific industry.

An audit is a snapshot in time and an auditor cannot possibly understand the culture, the management style, and the requirements best suited for a particular company in such a short period of time (2-4 day). Perhaps, the auditor may witness a process or procedure performed at another company that was successful and may share this information. The purpose is to initiate a thought process to analyze and evaluate if this process or procedure may work in their environment with their management culture and process requirements. An auditor is not permitted to demand that you comply with this process or procedure.

One example of how to proceed when a nonconformity that is not valid is received:

Nonconformity Issued:	An ISO registrar wrote nonconformity against a company that their forms are not in control because they did not have form numbers and were not controlled by revision or dates of approval.
Analysis of Nonconformity:	Once data is entered on a form it becomes a quality record and the record is controlled in accordance with the procedure for control of records. There was no basis found for this nonconformance in the ISO 9001 Standard.
Actions Taken:	The analysis was shared with the ISO auditor but the auditor did not accept the response. Therefore, the company requested that a higher department within the registrar review the nonconformity and that they provide specific ISO 9001 elements to support their nonconformity.

Result: The registrar changed the nonconformity to an observation for improvement that was based on a process that they had seen in other companies. The company thanked them for the suggestion but declined to revise their management system since it was working fine “as is”.

If the company had decided to comply with the auditor’s nonconformity that was not valid simply to expedite certification, then:

- The auditor would continue to mislead other companies with this requirement;
- Certainly they would forget to add a number or revision to at least one form that may result in future nonconformity according to their own specific (revised) procedure;

### **ISO 9001 is your company’s management system. Do not be told otherwise!**

**Never** let an auditor, consultant, employee who implemented an ISO 9001 program at his last company, or a customer tell you how your ISO 9001 system should be structured. The management team must define their own management system to meet the needs of their company and get the most out of it. This does not mean the management team cannot delegate responsibilities of implementing and maintaining the management system. It simply means the management team must define the management system and, more importantly, the expectations.

It is obvious to a third party ISO auditor when a company has defined their own management system versus when the management system has been written and provided to them. When a company defines their own management system, the ISO 9001 audit from the external registrar is simply a verification of the effectiveness of their management system and an opportunity for them to have a third set of eyes look at their management system and help them identify areas for correction and/or improvement. This process is always less painful when the management system is created by the management team using the Plan, Do, Check and Act approach.

In fact, auditors have a saying when they ask a question that is obviously outside the knowledge of the person answering. They say that the person questioned then has a look like a deer in front of car’s headlights at night. This “Blinded Deer” look is avoided when the ISO 9001 system is created by management through analysis and is representative to the company’s needs and requirements.

### **Summary**

#### **How you can ensure an effective ISO 9001 implementation**

- 1) Understand the requirements of the standard; this may mean sending key employees to a ISO Lead Auditor course, or general ISO training;

- 2) Define your own management system; this may require guidance from a consultant;
- 3) Once you define your management system, you need to own and defend your management system; this means it is okay to question and analyze the information when someone tells you to do something different;
- 4) Understand that your ISO 9001 system is in place to help you continually improve. If valid nonconformance is found in your management system (verified by analysis) then embrace this opportunity to improve your processes. Do it in a way that does not just fix the immediate problem but really identifies the root cause and initiates effective corrective action to the process.