

ISO 9000 and ISO 14000 Registration

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The quality standards movement really started gaining momentum around 1940, with military specifications. There were military specifications (MilSpecs) for everything. There was even a five-page military specification for chewing gum. Some MilSpecs addressed quality system management.

Quality groups began looking at these very seriously around 1960, including the military quality standards such as MilQ9858 and MilQ9858A. Without getting into all the specification numbers, suffice it to say that NATO published a standard, and the British Department of Defense published a standard. The British liked the NATO standard, so they copied it into their British DefStan standard, which itself went through further iterations.

By the mid 1960s, all these standards were floating around and being combined with other standards. About this same time, a Swiss standards organization decided to take all these quality standards and make them into one generic document that everyone could live with. They created ISO 9000.

In the late 1980s, the European Common Market decided they also wanted to adopt a standard, and they picked the Swiss ISO 9000 standard. Europe took the lead. They were not telling us what to do; not telling us how to run our quality systems, but simply adopting an international quality system for themselves. Consequently, for example, a company in France looking at suppliers in Spain or Germany, would know a great deal about the quality systems in place at those companies registered to the standard.

How are we involved? In Switzerland, ISO (International Organization for Standardization) is a kind of "U.N. of quality organizations". Our American National Standards Institute, (ANSI), is our representation on ISO in Switzerland. So in this country, ISO standards will have ANSI's name on them.

IOS, or ISO?

You're probably wondering why an organization named the "International Organization for Standardization" (IOS) would create a system named "ISO". They wanted a standard that would be applicable to everyone, putting everyone on an equal footing. The prefix for "equal" in Greek is "isos". They decided to adopt this Greek word for use in naming their new system. That's how the "IOS" named their system "ISO"! This is unintentionally confusing, but we have to live with it.

The most recognized quality organization in this country, the American Society of Quality, joined with ANSI in distributing and maintaining the ISO standard. It was a great common sense partnering of a standards organization and a quality organization. ISO 9001 in the US became ANSI/ASQ-Q91. In 1994 it became ANSI/ASQ/Q9001-1994, meaning that we've adopted ISO standard, agreed on an American version, and this is the 1994 version. The standard has been through several changes keep it up with the times. Currently, they are about to come out with a new revision of the ISO 9000 standard for the year 2000. Release is scheduled for November.

I'll explain later the difference between ISO 9000, ISO 9001, ISO 9002, etc. But for now, let's just call everything ISO 9000.

When my company was registered to ISO 9000 in 1993, we were among approximately 1400 ISO 9000-certified companies in the US and Canada. Today, there are 33,000. Obviously, a lot of companies have decided it is a good thing!

One thing you'll notice about the ISO 9000 standard, is its brevity. If you delete the introduction and the bibliography, the actual standard portion of the document is very short - only about six pages. These six pages are 'ruling the quality world' today. Whether you make french fries or missiles, you can use this standard as the basis of your quality system .

There are certain things that ISO 9000 is NOT. It is not a product standard; you won't see anything saying "This product is an ISO 9000-certified dishwasher". It is not a compliance standard: We comply with the law; We comply with the fact that we are not supposed to go through a stop sign; but, if you don't follow ISO 9000, you don't go to jail.

It is also not a performance standard. It does not tell companies how well they are supposed to do. Let's say that next year we want to improve our success rate for final test on an instrument from 98 to 99 percent. If we don't make it, we may be disappointed, but the standard does not have provisions for product quality. If you have an ISO9000 registered quality system, you WILL have documented methods of analyzing what went wrong, and corrective action procedures in place to correct the system where necessary.

So, what is ISO 9000? It's simply a designation which tells others that your company is running under universally understood ISO 9000 quality guidelines, which lets them know a lot about your company, its processes and its products. It puts you on an even footing with other companies using the standard.

There are several sections of the ISO 9000 standard, and whether you are registered under the standard, or just running your quality system in a way that *could* be registered, you are conforming with the standard in the same way that people conform in their dress or conform in hairstyle.

When an ISO inspector comes to a plant, he only comes if the plant is either (1) already registered to ISO 9000 or (2) they want to become, by virtue of his visit, registered to ISO 9000.

What does "ISO 9000 Registration" involve?

A company that has a quality system that they feel is operating under the guidelines of ISO 9000 can apply for registration. Then, a formal chain of events occurs. First, the company informs a registrar (a company that ISO has approved to evaluate company quality systems) that the company wishes to be audited (evaluated). Relevant company information is submitted to the registrar. A date is set for the audit. When the auditors visit, they compare company operations to the standard. If documented evidence shows that the quality system has been adequately implemented, and is operating as described in the standard, the company becomes registered. It's like passing the Bar exam. The auditors dig into the operations of the company, from CEO on down to bench technicians. They are looking for *objective evidence* that shows conformance to the standard.(They

don't usually go into Finance, because Finance is usually audited very aggressively by someone else.)

If the company doesn't meet requirements on the first audit, the Registrar will generate a list of non-conformances. Most registrars will give companies 30-90 days to submit in writing what they plan to do, to fix non-conformances. They come back to verify that the company indeed fixed them. When all is in conformance, the company becomes ISO 9000 registered.

After it is registered, the company will be re-audited, normally every 6 months. It is usually harder to get in the first place than it is to lose. No one personally fails under the system; nobody is 'written up'. Non-conformance is merely an opportunity for improvement. If the company is doing something that causes an auditor to issue a nonconformance, it only shows that the company may need to change that process. On the other hand, it may be a training issue. (What's the corrective action? Train the people and record the training.)

Overall, a company running their quality system in conformance with ISO9000 standards will be more capable of producing a quality product in a consistent manner.

Everyone has their bad days; companies have bad cycles. The important thing is to find out *when* things go *wrong*, and have a corrective action plan in place to make things go *right*. (That is almost as important as having things not go wrong in the first place.)

Internal Benefits of ISO 9000 Usage:

- *Better documentation* throughout the company.
- *Greater quality awareness* - everyone in the company has to be educated to some extent on what ISO is, the quality policy of the company, the mission of the company, and how the quality standard works as applied to their job.
- *Positive cultural changes.*
- *Increased operational efficiency and productivity.*
- *Enhanced company communication.*
- *Reduced scrap and rework expenses* - studies have verified that ISO 9000 adoption usually affects the bottom line in various positive ways.

External Benefits of ISO 9000 Usage:

- *High perceived quality. Your customer perceives that you have higher quality. You may not, but the perception is there. One of the criticisms of ISO 9000 in the early days was that I could make a cement lifesaver exactly to my specifications, and kill all my customers. They changed the standard in 1994, adding some validation into the process.*
- *Note: Validation is different from verification. Verification is when I make an overhead projector, I design it, it looks like what I designed, and it works like I thought it should work. Validation means, "Is this going to be OK in customer usage? If the projector is going to be used in Alaska, maybe I add insulation around the bulb for varying temperature extremes. I design that in, taking into consideration what the customer will be using it for. Those sections were put in ISO 9000 in 1994, hopefully to make the customer's wishes more integrated with the product.*
- *Improved Customer Satisfaction.*
- *Competitive Edge.*

- *Reduced customer quality audits. (If we want to hire a subcontractor to make sub-widgets for our product, we'll want to go to his company and do a quality audit. Look at his quality system. How does he handle customer complaints? How does he handle corrective actions? How is his documentation? Well, if he's registered ISO 9000, we don't need to do all of that. We know a lot about that subcontractor just by their conforming to ISO9000. This saves us a lot of time in our evaluation.)*
- *Increased market share. The competitive edge is only as good as the number of companies that don't have ISO registration.*
- *Quicker time-to-market. Efficiencies realized by being ISO 9000 registered will improve your entire product development cycle.*

ISO 9000 Specification Sections

Following are the main things you have to have up and running in your quality system to become ISO 9000 registered. In each area of concern, the ISO auditors are looking for something they can hold in their hand, or look at and examine, as objective evidence that your system is working:

| Area of Concern | What to Look for |
|-----------------------------|---|
| • Management | Is someone in your plant responsible for your system? |
| • Quality System | Is your quality system defined? Do you have a procedure outlining how your system is set up? Does each department - engineering, purchasing, etc. - have their own procedures? How do they number their procedures? Our HR department numbers them HR-1, 2,3, etc. |
| • Contract Review | Do you have a procedure on how you do contracts? Can you show some examples of your contracts? Do you use a standard form? What happens when a contract is amended? Who has authority to sign off on contracts? What do you do when a contract is amended? |
| • Design Control | Design control encompasses all your drawings, bills of materials, spec sheets -all the things that are put into the design of the product have to be controlled. Design review meetings should be documented (i.e., agenda, minutes, action items). What evidence do you can you show that design control is going on? Minutes of meetings, agenda items, action items list, drawings, specifications, etc. are acceptable evidence. |
| • Document Control | Do you define what documents are, and how they are controlled? How do you know that procedures are originals? A simple blue stamp saying "original" could identify it. Therefore, if a procedure has no blue stamp, it is a copy, not an original, and therefore may not be the latest revision. Does the document have a distribution list? How does distribution work? |
| • Purchasing | What are your purchasing procedures? |
| • Process Control | Have you established tests and procedures, making sure that processes are documented and up to date? |
| • Inspection/Test | How do you inspect and test your product? |
| • Control of Test Equipment | If you use multimeters, scopes, etc., how are they calibrated? How do you track the calibrations? |

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| <ul style="list-style-type: none"> • Control of Nonconforming Product | <p>If I buy parts for my product and some are bad, what do I do with them? Destroy them? Return them to the supplier? Fix them myself? Who controls this?</p> |
| <ul style="list-style-type: none"> • Corrective and Preventive Action | <p>What happens if something goes wrong? If wrong part comes in, or a complaint is received, who logs it? Who received it? Who gets copied on it? How do we document the actions taken to correct the situation, and prevent it from happening again?</p> |
| <ul style="list-style-type: none"> • Control of Records | <p>A lot of records are generated as the quality system operates. Contract reviews, design and control meetings, documents and drawings and bills of materials etc. Where do you store them? How do you store them? How long do you keep them? You have to have them readily available, kept from harm, safely stored, and they must be current. You have to either get rid of obsolete documents or mark them in some way as obsolete.</p> |
| <ul style="list-style-type: none"> • Internal Audits | <p>Do you have a system to police yourself? Do you perform internal audits to prepare for external audits? The first thing the external ISO Auditor will ask to see, is your records of internal audit.</p> |
| <ul style="list-style-type: none"> • Training | <p>Do you determine your training needs, and record the training that occurs?</p> |
| <ul style="list-style-type: none"> • Servicing | <p>Do you have policies governing contractual agreements? If you sell a service contract that obligates you to visit every 2-3 months, is this written down? How do you determine that the contract may be over?</p> |

The Makeup of the Standard

ISO 9000 is actually the name we give to the complete ISO system of quality standards. However, you may see companies that boast of being ISO 9001, ISO 9002, or ISO9003 registered. Earlier I promised to explain the difference between these designations. Why so many differing numbers? What do they mean?

There is actually a hierarchy of ISO designations, each with its own elements.

For a company to claim ISO 9001 registration, it must successfully pass all the above mentioned areas of examination. (Most companies seek ISO 9001 registration.)

The standard recognizes that some companies don't design what they build or sell. As a result, those companies have no design efforts ongoing. Section 4 of the standard, concerned with design control will not, therefore, pertain to those companies. ISO9001 minus the design control section becomes ISO9002.

If, on the other hand, your company is a sales and distribution concern that does not design or fix products, it will seek ISO 9003 registration. ISO 9003 omits Design, Service and Maintenance from the standard. The standard in this way becomes more of a "custom fit" for the operation of the quality system.

Hierarchical Documentation

By using a hierarchical documentation system, companies are able to modify documentation at one level without necessarily having to change documentation at all the other levels. Hierarchical documentation is a carefully managed method of organizing a company's documentation for maximum effectiveness and minimal upkeep woes.

As far as ISO goes, as mentioned above, there are about 20 sections to the ISO 9001 specification. All are fairly easy to comply with. You don't need an overabundance of paperwork to document your processes and procedures, but there is some technical writing involved, and you need to have some tech writing expertise.

There are four types, or levels, of documentation you will need to manage to achieve ISO 9000 registration. These four levels form a hierarchy. The more detailed the document, the further down it belongs in the documentation hierarchy:

The ISO 9000 Documentation Hierarchy:

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| • Level 1 | <i>What do we do?</i> | <i>Quality Manual</i> |
| • Level 2 | <i>Details of each quality policy - who does what, where</i> | Standard Operating Procedures (SOP's) |
| • Level 3 | <i>How?</i> | Work instructions. |
| • Level 4 | <i>Documents & Forms</i> Example: Database | Fourth Level documentation includes all the records and forms which are generated by the working system. |

ISO 9000 Document Generation and Change Control

- Under ISO 9000, every department issuing documents is free to designate its own procedures and channels for processing document change requests. You define for yourself what your distribution network is, and who has authority for sign-off and release of procedures.
- Authority - Who has the authority to sign off on documentation changes?
- Obsolete Documents - Describe what you do for these. Shred, archive, etc.
- Distributions - Who gets the documents?
- Identification & Revision - How do you identify documents? How do you track their revisions?
- Appendices & Forms - Do you include appendices, containing extra reference materials pertaining to each document?

Creating an ISO 9000 Quality Manual

If your company is ISO 9001 registered, it will need to keep and maintain a Quality Manual. Remember, this is the first or highest level of documentation in the system. What does ISO say should be in this manual?

ISO 9000 Quality Manual Contents

- Title, Scope and field of applications - i.e., What do you do?
- Table of contents - for ease of lookup
- An Introduction to the Organization - mission, quality statements, etc.
- Quality procedures and objectives - should be completely spelled out.
- Organization chart - always helpful.
- Definitions - how does your company define aspects of quality?
- Procedural sections - how does your company do things?

- Appendix that contains support data - can be helpful to insert added examples of forms, etc. However, be careful: if you put something in your quality manual here, it will probably need updating in the future, which becomes another procedure to document.

In working with ISO 9000 documentation, here are several tips to help you avoid making mistakes or overcomplicating your documentation:

Tips for Documentation:

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| • Keep it simple. | For an SOP, keep it short; two or three pages should suffice. Details belong further down in the documentation hierarchy. |
| • Standardize formats. | Set up, and document, your standardized formats. |
| • Flowcharts | These are nice to have. |
| • Avoid absolutes | Use 'normally' or 'on occasion' instead of 'will always'. Don't specify industry-standard lighting levels by the foot-candle, just say 'normal room light'. If you use absolutes in your documentation it can come back to haunt you. |
| • Track changes | Have a system for tracking your documentation changes. For example, cover pages can be used to note changes pertaining to each document. |
| • Documents versus Records: know the difference | A document is a type of procedure For example, a form, before it's filled out, is a document. A record, on the other hand, is objective evidence that something happened For example, a form, <i>after</i> it is filled out, becomes a record. |
| • Limit forms, if possible | Documentation is a necessary evil, but don't make this evil worse by over proliferating your forms. |

Nonconformances

What's an example of a non-conformance? What if I go to the HR department and say, I've talked to several individuals in your company, and they tell me they have attended a seminar, and I'd like to confirm that with your records because ISO 9000 says that you must record this activity. We pull up the people's training records, and I notice that for the 6 people I talked to, for two of them, there are no records, for three there are partial records, and only one has a fully documented record of the training. Something's wrong with your system. How do you define how you get these records down to HR?

Well, according to our HR SOP, the people attending classes are supposed to send us a copy of their certificates of completion, so we can put them in their file folders.

Something's not happening here; this is a non-conformance. As ISO Auditor, it is not my job to determine how to fix the problem; that is the company's job. When I come back in 6 months for a follow-up audit, I'll look at the training records again to ensure the company has addressed the problem and has either elected to follow the procedure as written, or amend the procedure in some way. I may elect to examine additional records to confirm this.

The quick fix is called corrective action. It's not necessarily bad; the company fixes up their training records to make them all correct. However, preventive action is more important: what will this company do processwise, trainingwise, or whatever, to make sure this never happens again. An example of a good preventive action would be for the company to change its SOP so that if a person goes to a course, we keep a record of the check that was cut when you went to the seminar, and we keep a record of the date of the seminar. Within one month of the seminar date our secretary calls up each attendee and asks for the certificate.

ISO 9000 does not tell you what kind of preventive action you must take; it only requires that a preventive action is documented and implemented. It's up to your company to decide what kind of preventive actions are appropriate.

The auditor needs to use good judgment in the evaluation process. He or she needs to look at procedures not only for their documentation, but also their implementation and effectiveness. Consider company's tape backup procedure calling for all tapes to be stored someplace off site. If in fact the offsite location is not adequately air conditioned, the tapes could be damaged by high temperatures. The procedure is documented and implemented as written, but it is not effective. ISO auditors need to always be looking for effectiveness as they evaluate a company's documentation and procedures.

An auditor may be auditing something he or she has absolutely no knowledge of. Take brain surgery, for example. I may know nothing about brain surgery, but I *can* ask the brain surgeon, "Were you trained? Can I see your training record?" I can also ask some other things. "You've got an autoclave here. An autoclave is used to sterilize instruments. Your autoclave has a calibration date on the back, because it must reach a certain temperature to sterilize the instruments properly. It looks like it is out of calibration by six months. Same goes with an EKG machine. How do I know if the EKG machine works? If the doctor breaks out the defibrillator paddles to shock my heart, I might want to ask, "Wait a minute, are those calibrated? Is there an expiration date on them?"

ISO 9000 does not require enormous manuals to be created. However it can take a lot of work to get up and running, and if not done right the paperwork can be an impediment. I personally look for ways to minimize ISO 9000 record keeping. For example, you can keep your records electronically with secure backups, instead of promulgating paper manuals. ISO doesn't really care how big your documents are, as long as you have documented the systems adequately. (Say what you do; do what you say!)

We had an engineer once who submitted an SOP that was 25 pages long. I told him he should be able to greatly simplify the document, and get it down to 10 - 15 pages. Who uses it, who gets it, who has access to the software - things like that. But he was including how to operate the software; all the way down to describing when and where to click the mouse to make the program operate. These items did not belong in a Level 1 SOP; they were Level 3 work instructions.

So, understanding the ISO 9000 document hierarchy is very important in reducing the amount of documentation.

Overall, ISO 9000 has been a good system. It has helped us greatly.

Richard Inch: "When I came to Inficon, I hated ISO 9000. I saw tons of paperwork. I had to write tons of SOPs, work instructions, documenting how my life works. Now, after five years, I couldn't imagine working somewhere that was not ISO certified. It's so nice to not only know what I want, but to be able to look at the specification and determine whether a change I want to make will affect other departments. If I want to know how my shipping department packs my manuals, I can look at their specs and immediately know whether the change I wanted to make is practical. As a result, confusion in the company is drastically lowered. This keeps people in the company from arbitrarily making changes without consulting others, building empires, and impeding others from working effectively. If you have someone with a phenomenal ego, he still will have to do his job according to his work instructions. He can't tell me, "well, I decided to do it differently." I have seen people in other companies do this just to confuse people. That kind of behavior is gone under ISO 9000. Those kinds of people don't remain employed."

What is ISO 14000?

ISO 14000 is the environmental management system (EMS) standard. It has similar sections to ISO 9000; it covers documentation control, training, management, record keeping, etc. only it covers the environmental arena. It challenges a company to decide for itself what its major environmental impacts are going to be, and decide on how it plans to address and document those impacts.

ISO 14000 forces a company to find out what regulations they are subject to, and to have effective procedures in place to ensure that they are in fact conforming with those regulations.

This can of course have a great impact on a company; if it knows it is environmentally compliant, and all of its suppliers are ISO 14000 certified, there is less chance of being drawn into legal problems.

Conclusion

Standardization of quality and environmental systems puts companies on a level playing field, and has the potential to help companies better manage their operations.

Companies adhering to the standard will be better equipped to put out quality product in a consistent manner, and to react to those situations where things go wrong.

Management systems like ISO9000 and ISO14000 are conformance standards, not performance or compliance standards. They are also not product standards. They are guidelines to effective and efficient system management.

When developed the right way, the system does not have to be a paperwork "nightmare." The three-tiered documentation structure should help in keeping the procedures and work instructions adequate but not over documented.

The bottom line: Say what you do.....and do what you say. (And be ready to prove it!)