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WHAT'S ISO9001:2008 REALLY ALL ABOUT?

Translating jargon into plain talk

May 2013

Believe nothing, no matter where you read it or who has said it, unless it agrees with your own reason and your own common sense. Buddha

When I came across this quote it resonated with me because, since 1991, it is exactly how I have been counseling folks to approach the ISO9000 series of quality management standards. While I know very little about Buddha, I don't think he was specifically referring to ISO9000, but then, I don't know that he wasn't. I did conclude however that he must have been a pretty smart person and it never hurts to be in alignment with really smart people.

Almost no one who comes to the ISO900 standard for the very first time does so without some preconception of what it is, what is says and how it works. For example, "It's all about saying what you do and doing what you say." "It's all about documentation." "It takes a lot to implement and almost as much to keep in motion." "It requires you to add a ton of overhead." "It tells you how to run your business." "It's about zero defects." "Having an ISO system doesn't prevent you from making junk." (The favorite one seems to be "cement life jackets".)

The kindest thing I can say about these is that even a broken clock is right twice a day.

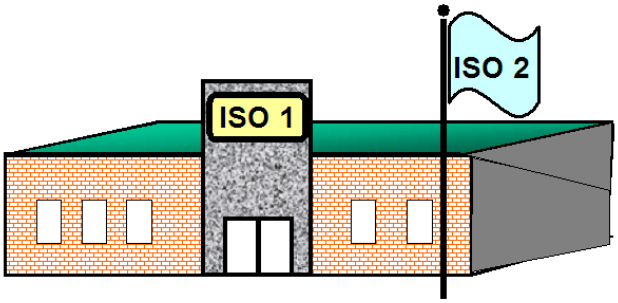
There isn't a single requirement in the standard that does not make good, common, business sense. If, after you have read this piece and gone through the standard yourself, you don't agree, one or two things may have happened.

1. We didn't explain it right, and/or
2. You over-read what it says.

Now, that's not to say that you will want to do everything the standard says you should do. After all, the standard does give you the option to exclude any of the product or service related requirements that don't apply to your type of business. So, in that regard, you may not need to do all of them.

And if there are others you choose not to do, it really doesn't matter – unless of course you have chosen to seek quality system certification by an accredited registrar.

THE TWO ISOs



There are two ISOs. We call one the "Building ISO." That's the one that is squarely and totally focused on stabilizing operations and results and satisfying customers. This one yields your maximum return.

The second one is the "Flagpole ISO": that's the ISO 9001:2008 registration certificate. Its value has nothing to do with quality but all to do with marketing. If you decide certification has value for you, realize you may have to do some the things

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you might otherwise elect not to do. There are probably not many of them and they are not especially onerous: it's just a matter of having to carry the extra baggage that comes with the certificate. Either way, you get to decide if the extra effort, if needed, is worth the potential return.

WHEN IN DOUBT, TRUST YOUR JUDGEMENT

BUILD A YELLOW BRICK ROAD

Wishing upon a star won't make all your dreams come true. But building a Yellow Brick Road to take you to your own Emerald City will.

Well maybe that's a bit of an overstatement, but it is a sure way to consistently and predictably realize the goals and objectives you set for your business or organization . You do it by building a path to your own success.

Now, you can either build the path to your own success or ……there is no "or" because without it, there can be no success.

ISO 9001:2008, the International Quality Management System standard, is a specification that defines the fundamental features and characteristics of an effective quality management system. It provides the framework for the Yellow Brick Road you will need to consistently and predictably produce and deliver the type of quality products and services that you need to satisfy your customers.

IT'S JUST FOR MANUFACTURERS RIGHT?

On the contrary, the standard and its derivatives apply to every type organization including manufacturers, service firms, consultants, distributors, social service providers, hospitals, schools, government agencies, etc. It applies in every market: e.g., aerospace, ice cream, medical, health care, electronics, IT, banking, and more.

ISO 9001:2008 PEDIGREE

The ISO 9001:2008 standard is the fourth iteration of the specs that were first introduced in 1987. What they contained back then was far from new. The original ISO 9000 series followed the British defense standard, BS5750, published in 1979. It, in turn, was patterned after the US Dept of Defense spec MIL-Q-9858A which went back to 1958.

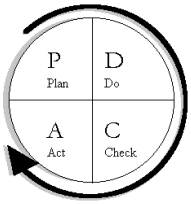
Though these specs and standards all claimed to be system-oriented and focused on quality assurance (proactive) instead of quality control (reactive), they were presented in such a way – like 20 unrelated commandments on stone tablets - that near total attention was paid to the details and almost none to the purpose. All the concentration was on the "trees" and little on the "forest".

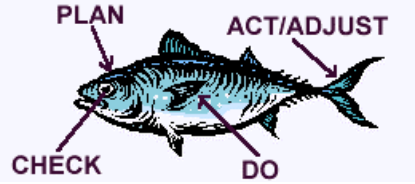
WHAT IS IT ABOUT

When the ISO 9001 standard was first issued it changed all that. While nearly all the details of the earlier specs are still in evidence, **the focus is on getting results**: the prime one being satisfying customers.

ISO 9001:2008 is "about" getting the results you want through planning, controlling and managing all the processes that are involved with satisfying customers.

Compliance with the standard is not the end but the means. (But see the cautionary note at Two ISO's.)
If the basic requirements of the standard are old, the principle on which it is based is even older.
The closed loop PLAN, DO, CHECK, ACT model was espoused over 60 years ago by Walter Shewhart, one of the original quality gurus and "father" of statistical process control. It was adopted later by Shewhart's disciple, W. Edwards Deming, who is considered to be the founder of Total Quality Management. (Though it is said that he never used that term.)





PDCA (AKA The SHAD)

No activity of any consequence happens that isn't planned. The plan is always followed. Progress and results are always monitored and, when not satisfactory, the plan is always adjusted. The SHAD says, "You gotta problem with that?"

ISO 9001:2008 took this principal and made one critical addition: continual improvement. If you are asking, "What does that have to do with quality?", remember that the standard is about getting the customer satisfaction results you identified and targeted. How long do you think you will have customers to satisfy if you don't keep improving? Do you really believe your competitors will observe the status quo? (See the article, The Status is Only Quo, When You Are Dead.)

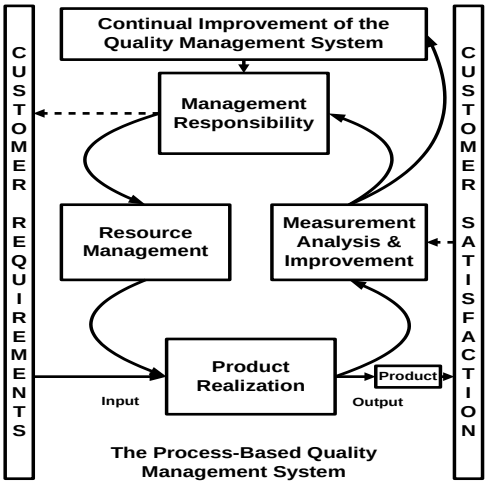
SONS OF ISO 9001:2008

Since its issuance, other quality system specifications have been amended to incorporate its process approach. Most notably, ISO 13485:2003 for Medical Devices and AS9100 for Aerospace adopted it verbatim, adding requirements that are specific to their respective industries and products. Other industry specific derivatives include lSO14000 Environmental Management Systems, ISO/TS16949 Automotive, and TL9000 Telecommunications. For the purposes of this article, everything we say about ISO 9001:2008 applies to these others.

THE PROCESS APPROACH

What, exactly, does the ISO 9001:2008 standard expect us to Plan, Do, Check and Act?

Our business processes, of course, because everything we do is a process or part of a process and it's only through the interrelationship of stable, effective processes that we reach our objectives. We control the processes that make up our quality system along with the inputs, outputs and interaction with other processes so that the entire process chain is controlled.



The Process-Based Quality Management System

Think of a championship relay racing team. Having the fastest runners isn't enough. Their baton handoffs must also be of gold medal caliber. (Anyone who watched our Olympic relay racing team's mishaps in Beijing saw ample evidence of that.)

The standard identifies four major process groups and depicts them and their interrelationship in this figure. Its principal requirements are summarized below.

Keep in mind, the standard gives you the system ingredients – the "What". The recipe – the "How"- is your call.

A Few Words from a Dutch Uncle. If your organization has little hands-on experience with comprehensive quality management systems in general or with the standard in particular, seek the assistance and advice of a knowledgeable practitioner with years of implementation experience for your type and size of operation. The more grizzled the veteran the better.

Those who ignore this advice usually over-read the requirements and, "just to be safe", add features with no added value and often with negative value. The affectionate term for this is Naming Your Own Poison.

A SUMMARY OF REQUIREMENTS

This is worth saying again. The standard only tells you **What** to do. It's entirely up to you to determine **How** to do it.

Management Responsibility

- Clearly identify what you (Senior Management) want your quality system to accomplish. (mission statement/quality policy).
- Establish metrics (or "discernables") that will tell you how well the system is performing at fulfilling its mission. Include subsidiary metrics at levels, functions or departments you feel are appropriate so they can track their performance, too.
- Communicate all this throughout the organization so that everyone understands what you want and how their performance can have a direct impact on the mission.
- Clearly define and communicate the responsibility and authority of all personnel whose work can impact quality.
- Appoint a management level individual to make certain the system is adequately planned around the process approach, complies with the standard and all other quality requirements that apply to you, is properly implemented and its performance reported. Describe the quality system (say what you do) in a Quality Manual being sure to identify the sequence and interaction among your core processes – so that everyone knows you understand the basics of the Process Approach.

- Prepare, implement and maintain the written procedures mandated by the standard (i.e. Control of Documents, Control of Records, Control of Nonconforming Product, Internal Auditing, Corrective Action, and Preventive Action) along with those needed to effectively control other processes.
- Approve and control documents so that only the proper versions are available when and where needed.
- Prepare and control records so that they are maintained for designated times, are legible and readily retrievable. (The standard identifies which records must be kept.)
- Regularly review performance of the system, examining both data and intangibles, and take remedial action when called for.
- Commit to taking a proactive approach to identifying specific opportunities and needs for improvement of products, services and/or the system.

Resource Management

- Identify personnel qualifications by function or job and use only qualified people to perform those functions/jobs effecting quality, Train them as needed. Assess training effectiveness.
- Provide appropriate, approved facilities and equipment. Maintained them to prevent quality problems.
- Provide a work environment suitable to the production of products and services.

Product /Service Realization

- Fully plan all production and service processes. Identify and provide necessary controls. Documents, such as procedures, work instructions, drawings, specs, etc., are controls and are to be created and used where appropriate.
- Review incoming orders or contracts to be sure the customer's needs and instructions are clear and compete. Verify your ability to meet order or contract requirements before you commit to them.
- Handle customer complaints in a systematic fashion.
- Control design activity. Assemble a design team. Know what you are designing. Identify measures for success. Review the work as it progresses. Verify that you did what you promised. Make sure it actually works. Control design changes.
- Evaluate suppliers in ways that are appropriate to the criticality of what is being bought. Buy only from suppliers you have evaluated and approved and whose performance meets your standards.
- Ensure that information contained in purchase documents provides all the information the supplier needs to fulfill your needs.
- Verify purchased product before use. (NB Inspection and test are not the only ways to verify product)
- Control the production of products and delivery of services per your plan. Keep processes stable.
- Validate special processes, i.e., processes whose output is not readily verifiable through inspection or test.
- Match the specs to the job.
- Keep track of what you make. Comply with any contract/regulatory requirements for traceability of product.
- Identify the acceptance status (acceptable or not acceptable} of purchased materials and items produced using, for example, inspection stamps, tags, competed travelers, etc.
- Report damage to or shortage of customer owned property – if any - when it arrives. Account for its use when required. Handle the customers' private or confidential data per any agreements you have with them.
- Handle, preserve, and package product to avoid damage or deterioration.
- Identify and calibrate equipment used to take acceptance measurements and/or check it against recognized international or national standards. Use it properly. Periodically check the calibration. Validate software used in the verification process and control changes to it.

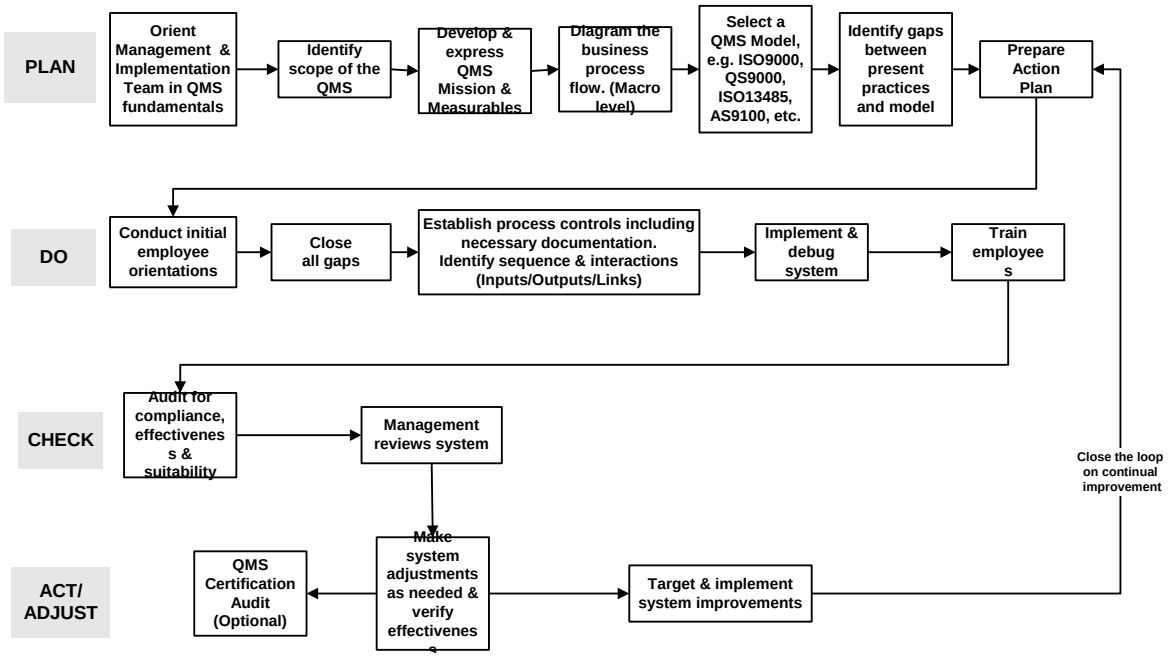
Measurement, Analysis and Improvement

- Monitor the effectiveness of all processes. (i.e. Are they in control? Do they yield the desired output?)
- Monitor and measure products and services against established criteria.
- Maintain and analyze data to assess system performance and spot trends, e.g. presence of potentially out of control conditions.
- Assess customer satisfaction from the customer's perspective.
- Conduct internal audits to verify system compliance and effectiveness.
- Control nonconforming product (and materials) to keep bad product away from good product and to figure out what to do with the bad product.
- When appropriate, take corrective action to identify and eliminate the causes of product or system nonconformances. Verify the effectiveness of the actions taken.
- Take preventive action when conditions exist which, if left unattended, are likely to lead to nonconformances. Identify the causes, remove them and verify the effectiveness of actions taken.
- Continually and systematically identify and pursue system and product improvements.

IMPLEMENTING ISO9000 IN YOUR OPERATION

If you are thinking about implementing an ISO 9001:2008 quality system or any of its derivatives, the first step is to compare your current practices with those required by the standard. This is known as a "gap analysis". If your organization has a record of consistently satisfying customers and if it runs in the black, you obviously have been doing a lot of things right. In that case, it is highly likely that your core practices are already in line with what the standard requires, making implementation fairly straightforward.

There is no rocket science involved. Anyone with average intellect and ability can, with experienced guidance, develop, implement, operate and maintain a fully compliant quality system that also adds value to the organization. Here is a typical implementation project



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Since 1991, Source4Quality, Inc. has been assisting organizations of every type improve the performance of their business operating systems and the quality of their products and services. We have worked with very small firms (1 to 10 employees) and larger ones, manufacturers, distributors, service firms, educational institutions and social service organizations encompassing for profit and nonprofit. We offer consulting and training on a broad range of disciplines including Quality system implementation, Internal Auditor Training and Internal Audit Outsourcing .

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