# Implementing an ISO 9001 Quality Management System: Climbing on the Bandwagon

***by John Orthaber***

While the ISO 9000 Quality Management System has been around since 1987 and it is generally acknowledged that the system produces some fairly significant benefits, including improved profitability, higher sales, and better employee morale, there are still a lot of companies reluctant to climb on the bandwagon. Some of this is likely due to skepticism – the belief it will not live up to its claims, but a lot of it is simply due to the lack of understanding: owners unsure how to go about implementing a system and thinking the implementation process will be too costly and too disruptive. They don't fully understand the system and they are looking for answers, including:

## What makes the ISO 9000 Quality Management System work?

In addition to the marketing advantages, which everyone seems to understand, there are a number of different aspects to the system that contribute to its success. Of these, three tend to stand out: the documented instructions, the third party audits, and the system requirements that lead to operational improvements.

The instructions ensure that the processes used for managing the basic functions of an organization are performed in the same manner regardless of personnel changes; they coordinate the activities of the various people responsible for implementing any given assignment; they demand employee involvement; and they are, in effect, contracts that can be used to hold employees accountable for their actions. They engage employees and add both control and accountability.

The third party audits add stability and sustainability. The system requires that a qualified unbiased third party registrar audit the complete system on a annual basis. Failing to correct violations cited in this audit can mean loosing your registration, which is a strong incentive for keeping the system active and up-to-date.

The audits, surveys, and data gathering system requirements serve to identify problems and opportunities. The management meetings and the corrective and preventive action requirements transform these problems and opportunities into improvements. The end result is it is very difficult not to make improvements.

It's not surprising that the ISO 9001 Quality Management System is the most popular management program on the planet.

## What is involved in the implementation process?

The implementation process is comprised of three discrete parts, including: 1) developing the documentation, 2) gathering and managing the historical information used for managing the system, and 3) implementing the physical and administrative changes needed in order to meet the requirements of the standard.

## The First Part: System Documentation

On the surface it may seem like developing this documentation should not be all that difficult. You must have a manual that includes a policy, objectives, scope, and an explanation of how the quality system processes interact. Plus, you must have written instructions for:

1. Managing the procedures and all the other system documentation
2. Managing the historical information (the records) associated with the system procedures
3. Conducting internal audits
4. Controlling nonconforming product
5. Implementing corrective action
6. Implementing preventive action

Section 4.2.1.d of the ISO 9001-2008 standard also hints at the need for additional documentation. It states that you shall include "*documents, including records, determined by the organization to be necessary to ensure effective planning, operation and control of its processes."* But the standard does not define these documents, and technically, aside from the manual and these six instructions, anything more is optional.

The reality, however, is if you want an effective and sustainable quality management system a significant amount of additional documentation is required. The system should establish consistency and eliminate misunderstandings, which is best facilitated with clear and unambiguous written instructions. Policies, which are a pervasive part of any system, have absolutely no value if they are not in writing; and enforcing accountability is extremely difficult if the responsibilities are not spelled out, all of which add up to a fair amount of documentation.

These documents are typically segregated into the following groups:

1. System Manual, which provides background information and explains how the system works.
2. Administrative Procedure Manual, which includes the procedures and policies specifically designed to explain how companies manage the system processes and how they intend to comply with the requirements of the ISO 9001 standard. These are the procedures and policies used to manage administrative processes like marketing, human resources, quality control, infrastructure, purchasing, engineering and design, inventory control, planning, etc.
3. Operating Instruction Manual, which includes the instructions that address the "job specific" manufacturing and service related activities like production, construction, repair, and assembly operations.
4. Reference Documentation, which are documents like industry standards, equipment maintenance manuals, corporate auditing guidelines, employee policies, etc. that define practices, procedures, or performance criteria not covered by the other documents. These can be either externally or internally generated.

My rules for developing this system documentation include:

**The System Manual:** Give them more than they ask for. The system manual sets the stage for the registration process. It is the starting point of the auditing process and it should explain what the company is trying to accomplish, how the quality system works, and how the quality system is controlled.

The standard requires a brief description of the operation, the quality policy, goals and objectives, system scope, an explanation of the processes used to frame the system, and an explanation of how these processes interact. In addition, the system manual is the best place to explain how the system is structured, who manages the system, and how it's managed. It is not the place for procedures of any kind.

**Administrative Procedure Manual:**

Rule 1. Include only administrative processes, but make sure to include all those important to managing your operation not just those required by the standard.

Keep in mind that the standard does not claim to be all-inclusive. For instance, it says little about inventory control, yet this is a major concern for most manufacturing companies and the process for managing inventories is a logical addition to the quality management system. The same can be said for product costing. It is difficult to develop the cost of quality if you are not costing your products. Nor is there anything in the standard for managing environmental, safety, or financial activities, all of which may have a significant impact on the way people run their companies.

Rule 2. Organize the Administrative Procedure Manual around your administrative processes (e.g. marketing, human resources, quality control, purchasing, etc.) whereby the processes are the chapter titles and the procedures, forms, and other documents used to support the procedures comprise the content of the chapters. The chapters may include any number of different procedures, e.g. the chapter on human resource may include individual procedures for hiring, training, and evaluating employees.

A common mistake is to try to format the Administrative Procedure Manual along the lines of the standard. Besides being difficult and unnecessary, it destroys the personalized character of the system and shifts the focus away from conditions that are unique to your operation. It would be highly unusual if your processes were identical to those used in the standard. The better approach is to build a system around the needs of your company and worry about whether all the requirements in the standard are accounted for when you are done. There is absolutely no value in trying to match your instruction numbers to those used for identifying the requirements in the standard.

Rule 3. Systems fail when the procedures are incomplete or hard to read.

The procedures should include a purpose, policies relevant to the purpose, an explanation why things are done the way they are done, and explanations of how things are done. They should read to the comprehension level of the employees using them, and they should leave absolutely no doubt as to who is accountable for the assigned responsibilities.

Rule 4. Use flowcharts and process maps with discretion. They are not the panacea some seem to think.

First, the majority of employees in most manufacturing operations do not know how to read them and one of my cardinal rules for writing administrative instructions is that everybody should be capable of reading and understanding all the instructions. Some of the best ideas come from people who are not actively involved with the instruction. It's mistake to sacrifice their input by confusing them with something they can't read. Second, both flowcharts and process maps have one intended purpose and that is to identify the flow of process activities. They do not show the creation and trail of records and they do not identify responsibilities or the hand off of responsibilities, both of which are critical to developing effective instructions.

Rule 5. Start the implementation process by developing the administrative instructions.

If you wait until the end of the implementation process to develop these documents, the tendency is to say "what you do." The better approach is to determine "what you should do," put it in writing, and then do what you say; which means thinking through and documenting the procedural changes before you implement the physical and administrative changes. The implementation process is an excellent opportunity to implement improvements.

**Operating Procedures:** Too many companies generate too much unnecessary documentation. The key to developing operating procedures is 1) understanding the balance between training and documentation requirements, and 2) knowing how much information is needed.

The standard requires employers to provide employees with the information needed to correctly perform their assigned responsibilities. Proof is either documentation showing they have been provided written instructions, or training records, which also verifies they have been given the necessary instructions.

The value of written operating instructions is they make it easier to hold employees accountable for their actions and from that standpoint, it is only necessary to document those aspects of an operation that are subject to error, misinterpretation, or misunderstanding. This normally can be done with a minimum of effort and without a great deal of detail. The information can usually be gleaned from past mistakes, employee comments, and common sense. It's always easier to add to instructions than to simplify lengthy complex instructions. The average employee rarely reads lengthy detailed instructions and instructions of this nature almost never get revised.

**Reference Documentation:** Reference documents come in many different sizes and shapes, there can be multiple copies of any given document, they can be scattered throughout the operation, and some are subject to frequent revisions. In order to ensure the proper use of these documents the system must include instructions that provide provisions for identifying, assigning, upgrading, and maintaining location control.

**Other considerations include:**

1. No two organizations have the same goals and objectives or do things exactly the same way. This means there are always some differences between the procedures and policies of different organizations. It also means "off-the-shelf" documentation that solves all of your needs doesn't exist.

2. The challenge to developing the documentation is to minimize the effort without sacrificing value and the best way of accomplishing this is to find examples of documentation that is well formatted, alter the content to fit your situation, and then fill in the missing parts. Ask your consultant or check the Internet.

3. Templates can be helpful, but they tend to work only with those requirements that lend themselves to generic solutions. Even at that, a generic solution may not be the best solution for your situation. Most do not take into consideration the related policies and it is highly unlikely they will include the type of explanations that are relevant to the unique conditions of your operation.

## The Second Part: Gathering and Managing Information

The standard states that records shall be maintained in the case of management review meeting

minutes (5.6.1); education, training, skills and experience (6.2.2); product validation and verification (7.1.d); inputs for product design and development (7.3.2); and calibration records (7.6). In addition, the compliance auditors will require "evidence of conformity" for all of the requirements included in the standard, which means you must be capable of providing the auditors with either physical evidence or documented records, and in many cases records are the preferable and sometimes the only option.

These records, which are the historical data used to manage the various system processes, provide a means of confirming that the quality system is controlled, customer requirements are understood, audits are conducted, customers are heard, problems are found and corrected, non-conforming goods are managed, suppliers are performing, products are traceable, and incoming goods are inspected.

The method of managing these records is generally some combination of 1) a file management program, 2) database files such as Microsoft Access, or 3) hard copy files, e.g., binders, file cabinets and manila folders. All of which have advantages and disadvantages.

**File Management Programs –** File management programs are typically tamper-proof and capable of handling a large volume of information. They are designed to be paperless systems. Assignments, authorization levels, and additions and revisions to records are keyed into the program, which, under certain conditions, trigger action commands that are communicated via email. A few are tailored to manage primarily ISO 9000 records, but most are universal in nature and designed to manage all types of records, which means the user is responsible for developing the forms and reports needed to manage specific types of records.

These programs are also expensive – most cost well over $1,000. They come with annual and sometimes monthly maintenance fees and there are usually costs associated with installation, the number of users, data migration, and training. Many have their own programming language which makes the user dependent on people with that language skill; and some are web based, which means the program is running on someone else's server. Generally, they are best suited for companies with a lot of employees dealing with a large volume of information.

**Database Files –** Database files are more flexible, easier to manage, and less expensive. Some can be purchased for under $100. You can either develop your own or purchase files that are programmed to deal with specific types of records including calibration, training, purchasing, auditing, and maintenance records. Files designed for conducting customer and personnel surveys are also available. Some can be downloaded over the Internet while others are available in the form of a CD.

The majority use Microsoft Access and run on a Microsoft Windows operating system. The cost is the cost of the files plus the cost of the Microsoft programs. The files are placed on a server and secured by whatever means is used to secure the server files. Changes and enhancements can be made by anyone who understands Microsoft Access. In most cases there are no user fees or reoccurring maintenance fees, and most existing database files can be transferred into the files with the migration functions of the Access program.

**Hard Copy Records –** While almost everyone ends up with some hard copy records; e.g., documents that can't be scanned, documents with signatures, and documents that are available to all employees; building a record keeping policy completely around paper documents is risky even for small companies. It's too easy to misplace documents that move from one person to the next; and it is difficult to manage information that is located in various files, in different offices, and assigned to different people. Responsibilities change hands and individuals tend to change the way information is gathered and filed. Manual record-keeping frequently results in unnecessary duplication, e.g., sales using a different customer list than the person keeping track of the customer complaints. It also makes

it difficult to gather, analyze, and disseminate information. File cabinets are not as accessible as computers and do not have the sorting, reporting, linking and analytical capabilities of database files.

### The Third Part: Physical and Administrative Changes

The final component of the implementation process is making the administrative and physical changes needed in order to comply with all of the requirements of the standard. These are all the things that have to be done to ensure that the products and services comply with the requirements specified by the customer, plus all the measures taken in order to improve the products and services and the processes used to produce the products and services. If they are required by the standard, then they must be implemented before the system can be registered. If they are unique to your operation and not cited in the standard, while they may be no less important to running your business, implementing the changes prior to registration is not mandatory.

Some of these include:

**Top Management –** 1) Identify the processes needed to achieve the company goals and determine how these processes interact. 2) Develop a company policy and company objectives. 3) Establish the key indicators needed to measure performance against the objectives. 4) Ensure that the resources needed to manage the system are available. 5) Conduct at least one management review meeting per the conditions outlined in the ISO 9001 standard. 6) Communicate system developments to all employees. 7) Demonstrate that the key performance indicators are measured, evaluated, and communicated. 8) Make sure the administrative systems are safe and secure.

**ISO Representative –** 1) Make sure the system documentation is sound and current and that changes to the system are approved before they are implemented. 2) Make sure relevant versions of applicable documents are available at points of use. 3) Make sure the auditors are adequately trained. 4) Develop an audit schedule and conduct audits on all of the system procedures. 5) Demonstrate that the corrective and preventive action processes are working.

**Human Resources –**1) Verify that all employees have a basic understanding of the ISO 9000 system. 2) Establish qualification criteria for all the administrative and operational job functions. 3) Prove that all employees meet the qualifications of their job functions, including the top-level executives. 4) Establish a training program for developing employee skills.

**Purchasing –** 1) Demonstrate that all of the primary vendors are qualified and their performance is routinely evaluated. 2) Prove that material specifications are verified before they are released to vendors.

**Sales/Customer Service –** 1) Demonstrate that customer feedback is gathered and analyzed, including records of complaints. 2) Prove that processing capabilities are reviewed before orders for new products are confirmed.

**Engineering –** 1) Demonstrate that the information released to production is current, accurate, and complies with customer requirements. 2) Demonstrate that product changes affecting form, fit, or function are not implemented without customer approval. 3) Demonstrate that the critical performance characteristics are verified and validated before product changes or new products are released to the market.

**Planning –** 1) Demonstrate that the capacity to produce the product or provide the service in accordance with the terms of the order is available. 2) Prove that you provided the personnel responsible for producing the products or providing the services with the information needed to

fulfill the terms of the order.

**Production –** 1) Establish a calibration program that complies with the requirements of the standard. 2) Demonstrate that machinery capabilities have been validated. 3) Prove that nonconforming materials are not mixed in with conforming materials. 4) Prove that shipments comply with the customer requirements. 5) Prove that incoming materials comply with purchase specifications. 6) Demonstrate how materials with shelf life are managed.

System documentation and information management are the paperwork part of the system. These physical and administrative changes are the action part and represent the part of the implementation process that makes the system work. It's the part where you make sure your employees are actually complying with the requirements of the standard and where you create an infrastructure that allows them to do what they need to do.

## How long does it take to implement a system?

It's my experience that the implementation process is normally less complicated and goes faster in small and mid-size companies. Ten to fourteen months is typical for the average mid-size manufacturing company – loosely defined as 50 to 300 employees. Anything more is an indication something is wrong. Under ideal conditions it may be possible to register a small company in as little as six months. Controlling factors are the nature of the approach, available resources, having the right people in the right places, and the extent of the commitment by upper management.

Large companies should be able to implement a system in less than two years and they can frequently do it a lot faster than that. It depends on the complexity of the business, number of divisions, and number of locations. In many cases the implementation process can be speeded-up by independently registering individual parts of the company; including locations, divisions, or even departments. This breaks the task down into smaller more easily definable parts and allows a company to work on more than one part at a time. It also makes it possible to put off implementing the parts you are not yet ready to tackle while still acquiring certification on other parts.

Staying on schedule is largely a function of the amount of implementation experience you have. The standard contains fifty-two different compliance requirements, which in turn include around one hundred and thirty-five "shall statements." With some exceptions, regardless of the size of the company or nature of the business, you must comply with all of them.

## How much will it cost?

Almost all of the implementation costs fall into one of the following categories:

1. Registration Costs: Registrars are free to set their own rates, which are generally predicated on a daily rate per man plus expenses. This means the cost is dependent on the registrar chosen and the location of the registrar. Implementation is a two-audit process: a desk audit and a compliance audit, which means a least two trips, and if the system is complex the compliance audit may require more than one auditor. Most companies feel lucky to get away with anything less than $1,000 per trip. Implementation registration is a one-time event but keep in mind the system has to be re-registered on an annual basis.
2. Consulting fees and expenses: The cost and the quality of these services can vary over a wide range. In addition to providing advice, consultants can prepare the documentation, provide

database files for managing system information, and perform some of the training. The majority bill their services against measurable deliverables, e.g., the completion of the gap analysis, the completion of the manual, progress payments against the administrative procedures, etc. Writing the administrative procedures is normally the most difficult and the most expensive part of the project. Companies with the time and resources to write their own procedures can usually save some money.

3. Training: There are two types of training costs to consider: auditor training and job-performance training. Depending on whether or not the performance training is needed in order to meet a requirement in the standard or simply for enhancement purposes, it may be possible to defer some of these costs until after the registration process. However, if you don't already have a certified internal lead auditor on the payroll, the auditor training cost is unavoidable and will likely cost somewhere between $1,200 and $1,900. Organizations requiring several internal auditors can sometimes save by qualifying a staff person for use in training new auditors.

4. Internal labor: Consultants can provide advice, prepare some of the documentation, and help conduct surveys but the customer is almost always responsible for collecting and managing the system records, writing the operating instructions, conducting internal audits, and implementing the administrative and operational changes. The amount of internal labor needed is normally a function of the size and nature of the organization. The bigger and more complex the organization the more internal labor needed.

   The standard requires the appointment of an ISO Representative, which must be a staff member who reports directly to the person in charge of the organization on all matters relating to the management of the system. It normally is a part-time job for most small and mid-size companies.

5. Expenses: With some exceptions, the expenses associated with implementing a system are minimal. They typically include office supplies, inexpensive software, signs and banners, and housekeeping supplies. Some exceptions include expensive software, computers and communication networking, and layout changes needed to accommodate material management and housekeeping requirements.

## Conclusion

The secret to successfully implementing an ISO 9001 quality management system is understanding the scope of the project and having 1) the right attitude, 2) an implementation plan, 3) an understanding of how to write and organize the administrative procedures, and 4) a good adviser.

Attitudes are contagious and if the leaders and managers are not perceived as approaching the project with a positive attitude, the feeling will filter down to the employees responsible for implementing the system and ultimately to all the employees. It makes the implementation process more difficult and diminishes the quality of the system. A written implementation plan establishes the starting and ending points and defines the benchmark activities. It's what keeps the project on track. The administrative procedures are a reflection of the company's personality. They determine how the company complies with the requirements of the standard, creates accountability, and provides administrative efficiencies. Employee interest is directly related to the ability of these procedures to communicate effectively. And finally, the ISO 9001 standard is not a guidebook. It defines the "what" but not the "how," and as you might gather from this report, the 'how" involves a somewhat complex tangle of implementation activities. A good adviser is usually invaluable.

Given all these considerations, implementing a system is nevertheless not overly difficult or extremely expensive and the rewards more than pay for the effort. Now might be a good time to climb on the bandwagon.

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