

Just the Facts

Before transitioning to ISO 9001:2015, first take the time to understand how the standard is structured around seven quality management principles.

Allocate enough time and resources to properly plan and set realistic deadlines. Management must be there to provide adequate support, including the resources necessary to meet the project goals and deadlines.

Don't overlook the importance of finding the right registrar early in the process.





Under the Wire

Last-minute advice to successfully implement or transition to ISO 9001:2015 | by Mark Durivage

As the deadline to transition from ISO 9001:2008 to ISO 9001:2015 approaches later this year, there are many organizations still asking the question, “How do we get certified successfully?”

The answer is not as straightforward as you might think. Much preparation and thoughtful planning must occur to address a process that can be complex and confusing for some organizations.

But before looking at ways to make the implementation or transition as smooth as possible, it’s helpful to understand how ISO 9001:2015 is structured—namely, around seven quality management principles (Figure 1, p. 27).

Seven principles of ISO 9001:2015

1. Customer focus

Customer focus is probably one of the most important of the seven quality management principles. Without customers, organizations cannot survive. Today, more than ever, customers have ready access to choices due to the proliferation of the internet and social media. When organizations supply products and services that fail to meet customer needs and expectations, customers will migrate to products and services provided by competing organizations.

Understanding customer needs (current and future) will contribute to the sustained organizational success through increased customer perception, satisfaction and loyalty. Understanding customer requirements (stated and unstated) is not only a good idea, it's also an ISO 9001:2015 requirement.

2. Leadership

Leadership is charged with the task of aligning the organization's tactics, strategies, policies, processes and resources to achieve its objectives with the purpose of increasing effectiveness and efficiency by ultimately enhancing the customer experience.

Leadership not only involves the top management of an organization, but it also includes middle management, supervisors and workers. An organization with leadership that leads by example and empowers its people will continuously improve and meet the needs of customers and other interested parties.

3. Engagement of people

For an organization to be successful and enhance its capabilities, the organization must create and deliver value by engaging its people. The engagement of employees is necessary for organizational survival. Employees who are engaged will contribute to the organization's accomplishment of goals and objectives. Disengaged employees will not support organizational goals and objectives.

Engagement can be accomplished through communication and empowering employees by delegating responsibility for processes they own. Offering professional development and training opportunities is an excellent way to engage people and motivate them to their fullest potential.

4. Process approach

The process approach in a quality management system (QMS) can help organizations understand and meet requirements consistently, attain effective process performance, and improve processes based on evaluation of data and information.

Systems are comprised of processes; processes are comprised of subprocesses; subprocesses are comprised of tasks; and tasks are comprised of subtasks. For a system to properly function effectively and efficiently, the processes, subprocesses, tasks and subtasks must be inter-related. The output of one process can be the input for the next process. Basically, a process can be defined as value, which is added to an input with the result of an output.

The process approach also helps integrate ISO 9001:2015 clause requirements into an interrelated system in which all the subsystems (clauses) are mutually supportive and complementary to one another. The process approach will help reduce or eliminate the silo effect caused by processes that are not mutually supportive and complementary to one another.

5. Improvement

An ongoing focus on improvement is necessary for organizations to survive and thrive. What is acceptable today may be unacceptable tomorrow. Maintaining performance levels, reacting to changes in internal and external risks and opportunities, and creating opportunities for the organization are among the benefits of continual improvement. Benchmarking is a commonly used tool to evaluate the organization's policies, procedures, practices, processes, products and services.

6. Evidence-based decision making

Evidence-based decisions using data analysis are generally more effective than using just anecdotal information. Even evidence-based decisions contain a degree of uncertainty. Making data-driven decisions can help reduce the level of uncertainty, which leads to a higher level of confidence in the decisions being made.

In turn, good decisions lead to good results. Statistical process control, capability studies, design of experiments, correlation analysis, linear regression, hypothesis testing, trend analysis,

cause and effect diagrams and Pareto analysis are just a few tools that can be used to make evidence-based decisions.

Evidence-based decisions also can support risk-based thinking, a new concept introduced in ISO 9001:2015. Risk-based thinking is crucial for the development, implementation and improvement of a QMS. Risk-based thinking is really a two-step process. First, the organization must identify, analyze, evaluate, reduce and accept risk. Next, the organization must recognize and exploit opportunities by increasing the effectiveness of the QMS.

Risk-based thinking will allow an organization to focus its efforts on consistently providing products and services to meet customer requirements and expectations, while also enhancing customer satisfaction. Applying risk-based thinking allows an organization to focus and apply resources in an effective manner.

7. Relationship management

For organizations to be successful, they must manage their relationships with relevant interested parties, another new concept introduced in ISO 9001:2015. Interested parties can be defined as those parties (individuals, companies, groups, communities and government) that present risks to the organization's future if their expectations and needs are not met. They can include employees, shareholders, investors, customers, suppliers, regulators and the community.

Poorly managed relationships can be disastrous and negatively affect the organization. Relationship management helps ensure communication between interested parties, which can optimize these parties' impact on the organization's performance and facilitate a mutual understanding of each other's requirements and positions.

Interested parties is more than customer focus. Understanding the context of the organization—yet another new concept introduced in ISO 9001:2015—is identifying interested parties. Understanding the context of the organization determines factors that influence the organization's purpose, objectives and sustainability. This process considers internal

FIGURE 1

Quality management principles



and external factors. The context of the organization can provide guidance for the organization for tactical and strategic decisions, and help develop, deploy, monitor and maintain the organization's vision, mission, policies and objectives.

Considerations for getting certified

The first step in implementing, transitioning or updating a QMS begins with understanding the requirements and expectations of the standards and registrars. It's highly recommended to purchase a legal copy of the following documents:

- + *ISO 9001:2015—Quality management system—requirements.*
- + *ISO 9000:2015—Quality management systems—fundamentals and vocabulary.*
- + *ANSI/ISO/ASQ 9004-2009—A quality management approach—managing for the sustained success of an organization.*
- + *ISO 10002:2014—Quality management—customer satisfaction—guidelines for complaint handling in organization.*

- + *ISO 19011:2011—Guidelines for auditing management systems.*

Read them and make sure they are understood by those responsible for the QMS. Again, make sure that you purchase the actual documents. They are copyrighted materials. Downloading “free” copies is illegal, and they may not be the actual standard.

If these standards aren’t thoroughly understood, it’s unlikely your organization will be able to demonstrate compliance, and your chances of getting certified will be diminished.

One approach may be to use a consultant well versed in the standard and its application to your industry. There are likely many consultants who thoroughly understand the standard requirements, but there may be only a few who can apply the standards to your industry. There’s one local tattoo parlor that advertises: “A good tattoo ain’t cheap, and a cheap tattoo ain’t good.” In other words, you get what you pay for.

If your organization is considering using a consultant, ask him or her for references from other organizations that he or she helped

Certification Considerations

CONSIDER THESE POINTS TO COMPLY WITH EACH OF THE 10 CLAUSES CONTAINED IN ISO 9001:2015.

- 1. Scope:** When determining the scope of the quality management system (QMS), consider the processes necessary for improvement of the system, and conformity of products and services by meeting customer expectations and compliance with applicable statutory and regulatory requirements. This is also the place to state that the QMS is compliant with the requirements of ISO 9001:2015.
- 2. Normative references:** *ISO 9000:2015—Quality management systems—fundamentals and vocabulary* should be purchased and understood. Best practice is to use the concepts and terminology where applicable to provide consistency. This also is a good place to list the standards necessary to develop and support the QMS, including:
 - + *ISO 9001:2015—Quality management system requirements.*
 - + *ISO 9000:2015—Quality management systems—fundamentals and vocabulary.*
 - + *ANSI/ISO/ASQ 9004-2009—A quality management approach—managing for the sustained success of an organization.*
- 3. Terms and definitions:** *ISO 9000:2015—Quality management systems—fundamentals and vocabulary* should be purchased and understood. Best practice is to use the concepts and terminology where applicable to provide consistency. This is also a great place to include any organizational terms and definitions.
- 4. Context of the organization:** The context of the organization should be documented. Consider the interested parties and their needs, and how the organization will address their needs. This section also discusses the QMS and its processes. This is an appropriate place to identify the key parties and processes necessary to support customer satisfaction.
- 5. Leadership:** This section is a good place to determine management’s responsibility and determine the quality policy and objectives. One way to help comply with this section is to develop an organizational chart and job descriptions that clearly delineate responsibilities and authority.
- 6. Planning:** The organization should consider the risks and opportunities for the entire organization. Risks and opportunities can be identified and documented using strengths, weaknesses, opportunities and threats analysis and political, economic, social, technological, legal and environmental issues analysis. Quality objectives should consider and include the key process performance measures identified in *Section 4—Planning*.
- 7. Support:** Demonstrating employee competence by using task-based training is the best method to comply with awareness requirements. Best practice is to maintain a training matrix,

to implement a QMS or to transition to the updated standard. Request references from organizations of similar size, industry and complexity so you can make an informed decision on experience, training, education and cost.

If your organization decides to use internal personnel to develop and implement a QMS, it's essential that those responsible be appropriately trained and, more importantly, afforded time to complete the work. Your organization should consider the costs associated with using internal resources versus

the costs of hiring a consultant.

Effectively planned project management and—above all—reasonable exceptions by top management are crucial to successfully securing ISO 9001:2015 certification. The organization should realistically expect the certification process to take between six to 12 months. Anything less than that will probably result in several certification audit nonconformances, which will delay the issuing of an ISO 9001:2015 certification.

Furthermore, a poorly planned and rushed implementation will probably result in a strained relationship with the organization's registrar.

which indicates the employee level of competence for each job or function.

Monitoring and measuring resources (calibration) is best supported by a spreadsheet or computer program that provides a visual calibration status. Using a document change order (DCO) form and index is a great way to manage document and engineering changes. The form should include a checklist of consideration and activities to ensure changes will not have an unintended negative impact on products, services and the QMS.

- 8. Operation:** One of the best practices is the integration of the work instruction in the batch record. This helps ensure the most recent work instruction is available at the point of use and the employees are using the documentation. Many organizations also use photos in the work instructions to clarify specific tasks, including inspections. Photos also are used to document quality alerts to make the operators and inspectors aware of previous quality issues.

Maintaining a risk-based supplier program is a good way to focus the organization's limited resources where they are needed most. Creating a

grid listing supplier risk (low, medium and high) and applying more controls to high-risk suppliers is an effective way to manage supplier and receiving inspection requirements.

9. Performance evaluation:

Performance evaluation should include a comprehensive internal audit program using the process approach that audits by the key processes identified in *Section 4—Planning*.

A standardized agenda and minutes for management review are necessary to ensure compliance with ISO 9001:2015. I suggest adding more topics, including an assessment of the context of the organization, interested parties, and whether there are any new risks and opportunities.

Using an action item log is a great way to provide visibility to actions assigned during management review and prevents the action items from slipping away.

- 10. Improvement:** An issue management log is a valuable tool to capture audit findings, nonconformance reports, supplier corrective action requests and complaints. The log is most useful when due dates are assigned, and color coded to indicate their

status. Additionally, using the specific, measurable, achievable, relevant and time bound approach is a good way to determine verification of effectiveness requirements.

Although ISO 9001:2015 does not require a quality manual, I strongly suggest creating one. The manual provides a good, high-level overview of the QMS and can help employees understand the processes and their interactions. Additionally, a quality manual is a great tool to provide customers and potential customers during audits. The quality manual also is a great place to include a compliance matrix. The purpose of a compliance matrix is to provide a table of the ISO 9001:2015 requirements and where they are addressed. ISO 9001:2015 also does not require the appointment of a management representative.

Again, I strongly suggest appointing a designated individual to the role of management representative (usually a person from the quality function) so that consistent messaging can be maintained during certification, registration and supplier audits.

—M.D.

Best practice is to include a discussion and assign project responsibilities during regular management meetings. If already certified, record the responsibilities in the management review minutes or action item log.

Another piece of advice when transitioning to ISO 9001:2015: Get buy-in from those who will be affected. It is important to include the affected team members in the implementation process. Share with them the risks of not having the certification and the opportunities the organization may enjoy after becoming certified.

Management also must fully support the certification process by being actively engaged, providing resources necessary for a successful implementation or transition, and keeping the entire organization informed of the project's status. As an auditor, it's easy to identify whether management is involved and engaged. Just because they attend opening and closing meetings does not guarantee they are involved and engaged.

Customization is critical

From my experience, purchasing an off-the-shelf ISO 9001 system rarely works. Of course, in my consulting practice, there are "canned" procedures. But procedures always must be modified to fit the situation. Certain processes require less customization, including:

- + *Clause 6.1—Risks and opportunities.*
- + *Clause 7.1.5—Monitoring and measuring resources.*
- + *Clause 7.2—Competence awareness and training.*
- + *Clause 7.4—Communication.*
- + *Clause 7.5—Documented information.*
- + *Clause 8.7—Nonconforming outputs.*
- + *Clause 9.1—Monitoring measurement analysis and evaluation.*
- + *Clause 9—Internal audit.*
- + *Clause 9.3—Management review.*
- + *Clause 10.2—Corrective action.*

Certain subsystems require more customization, such as:

- + *Clause 7.1—Resource management.*
- + *Clause 8.1—Operational planning and control.*
- + *Clause 8.2—Requirements for products and services.*
- + *Clause 8.3—Design and development of products and services.*
- + *Clause 8.4—Externally provided processes, products and services.*

- + *Clause 8.5—Product and service provision.*
- + *Clause 8.6—Release of products and services.*

Processes that require more customization need an active, hands-on approach by the organization. These processes must be understood and documented. Consultants who say, "This is the way it should be done" are not doing their job. I have seen many QMSs that were implemented by consultants that were not fully embraced, resulting in a QMS that was literally the square peg in the round hole with less-than-favorable results. Even if the organization is not currently certified with documented processes, there are still processes and interactions in place that must be thoroughly understood.

An additional consideration is that, "One size does not fit all." A QMS for an organization with 20 employees will probably not suffice for an organization with 200 employees, just as a QMS for an organization with 20 remote employees will probably not work for an organization with 20 employees at one facility.

Organizations with multiple facilities also should consider a common QMS. One advantage of this is when corrections are made due to audits and customer complaints, for example. Corrections can be deployed to the entire organization, potentially preventing the same issues at other facilities.

The right registrar

Choosing the proper ISO registrar is also extremely important. Make sure the registrar is accredited by a reputable third-party accreditation agency. For example, ANSI-ASQ National Accreditation Board is the most widely recognized third-party accreditor for QMSs.¹

I recently encountered my first organization that used an unaccredited registrar for ISO 9001 certification. While preparing for the audit, I noticed the organization's quality manual was last revised in 2006, and the ISO certification was for ISO 9001:2008. This was my first experience with a "certification mill." The way this unaccredited registrar worked was the organization had to send a check along with its annual internal audit, and magically, a certificate would arrive a few days later.

The registrar also should be investigated to ensure it has the auditor expertise that aligns with the organization's products and services. For example, it would not be appropriate for a certification auditor with a customer service background to audit a manufacturer of printed circuit boards. Have the registrar

A Successful Implementation



provide organizational references for companies that are of similar size, industry, and complexity so an informed decision that considers experience and cost can be made.

Planning required

The key to a successful implementation of or transition to ISO 9001:2015 is proper planning with realistic deadlines and management providing adequate support, including the resources necessary to meet the project goals and deadlines.

Thoroughly investigate any consultant that may be used, research the registrar and contract with the registrar early in the process because it may have certain expectations to help ensure a successful certification. **QP**

NOTE

1. To verify whether a registrar is accredited, visit <http://anabdirectory.remoteauditor.com>.

Recently, a small manufacturing organization was looking for help setting up an initial ISO 9001:2015 quality management system (QMS). When I arrived, I was given a binder of templates, forms and procedures purchased online. The quality manager explained he had invested between 60 to 80 hours modifying the documents, and asked me to help finish the project and get the organization certified. The organization was also adamant about only including certain portions of the business in the scope of the QMS.

To begin the project, I recommended a highly reputable ISO registrar I had worked with in the past. The quality manager was skeptical, but I assured him the registrar was accredited by the ANSI-ASQ Accreditation Board. Getting the organization to agree to use this registrar was the deciding factor for me to accept the project.

By the way, did I mention the organization needed the certification yesterday?

From there, I explained that the most significant aspect of successfully developing, deploying and ultimately becoming ISO certified is two-fold:

1. Management must want the certification to improve the business—and not just to post a paper on the wall or website.
2. The organization must be included in all aspects of the QMS development. If a QMS is dumped in the organization's lap, the organization will never be fully and effectively implemented. That is why a consultant must also be a teacher, coach and mentor, and he or she must be patient.

As a consultant, the point at which I become confident that the project will be successful is when those responsible for the QMS began asking the right questions. For example, should this nonconformance be elevated to a corrective and preventive action? Should there be additional management reviews? Even though it is not required in the standard, should we proceduralize the process? For me, that is the most satisfying aspect of the project.

Another challenging aspect is having the organization map its business processes. As a consultant, there is only so much you can do without the client fully understanding how the business process works. After the business processes are mapped, recommendations to enhance and document the processes become easier. This phase of the project is always the most resource intensive, especially by the organization's staff.

Eventually, this small manufacturer received its initial ISO 9001:2015 certification without any findings from a tough auditor. —*M.D.*



Mark Durivage is managing principal consultant at Quality Systems Compliance LLC in Lambertville, MI. He earned his master's degree in quality management from Eastern Michigan University in Ypsilanti. He is an ASQ fellow and holds several ASQ certifications, including quality auditor, biomedical auditor, HACCP auditor, pharmaceutical good manufacturing practices professional, Six

Sigma Black Belt and manager of quality/organizational excellence. Durivage also authored and edited several ASQ Quality Press books.