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QUALITY

What is ISO 9001:
How can the latest 2015 revision
help your business succeed?

WHITE PAPER

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Executive Summary

The international standard for Quality Management Systems (QMS), called ISO 9001, was published by the International Organization for Standardization (ISO) in 1987. Before it could become an internationally recognized standard, ISO 9001 had to be agreed upon and accepted by a majority of ISO member nations. The most recent update is ISO 9001:2015, which was launched in September of 2015.

Written by leading quality management experts, ISO 9001 is suitable for implementation in any organization: big or small, for-profit or not-for-profit, private or government. When implemented correctly, organizations can also become certified against the standard. This means that one of the independent certification bodies has verified that the organization successfully implemented a Quality Management System according to ISO 9001.

An ISO 9001 certificate means that potential customers do not have to audit a company's processes; this audit has already been completed internally by the company itself, as well as by an independent external (certification) auditor. For this reason, ISO 9001 is critical for many businesses to be competitive in the marketplace.

And, its reach goes even further: because ISO 9001 is such an important and fundamental standard, it has been used as the basis for other industry-specific standards, including the automotive industry's ISO/TSA 16949, AS9100 for aerospace, and ISO 13485 for medical devices.

A recent survey indicated that despite the worldwide recession, more and more companies are making the decision to implement an ISO 9001 Quality Management System every year.

Number of ISO 9001 certificates per year
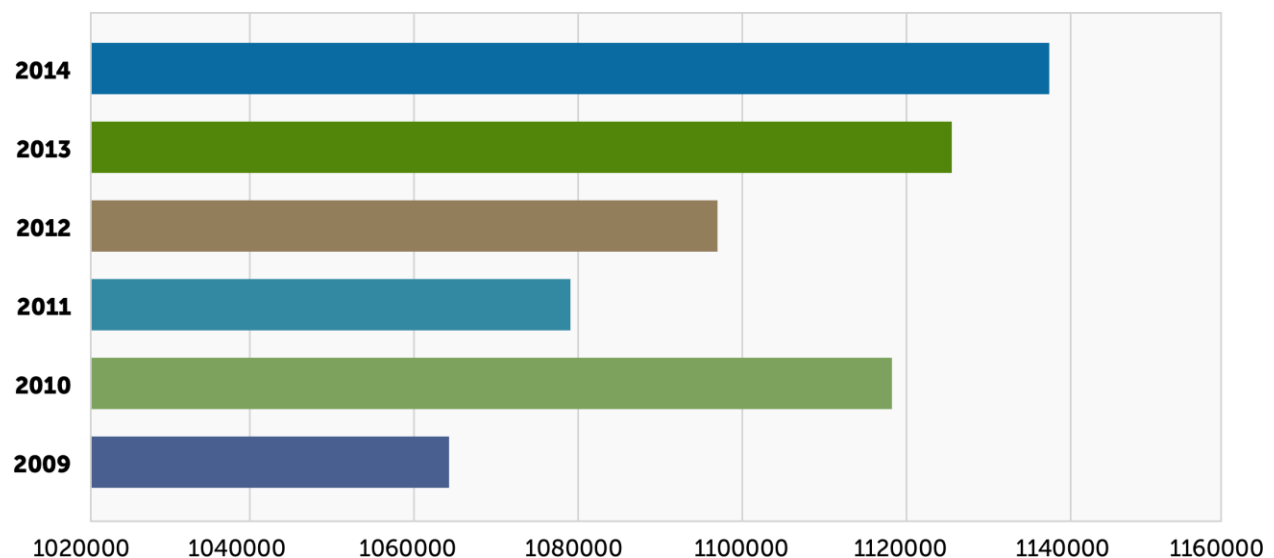
Source: ISO survey

Included in the ISO 9001 family of documents are ISO 9000, which defines the terms and basic principles of ISO 9001, and ISO 9004, which offers guidance on how to more effectively implement an ISO 9001 Quality Management System.

What is a
Quality Management System?

A Quality Management System, or QMS, is a set of documentation that includes processes, procedures, policies, and records. These documents describe the rules within a company that prescribe how products or services are created and provided to customers. A successful QMS needs to be designed around the specific requirements of the company and its products and services, but ISO 9001 can serve as a guide for companies during implementation, so that all important components are present in the QMS.

Recent changes in ISO 9001

The new revision of ISO 9001 was published in September of 2015, and it brought a number of major changes:

Structure – Similar to other ISO standards, like ISO 27001, ISO 9001:2015 has adopted Annex SL. ISO 14001 also recently adopted the same structure. This structural change makes ISO 9001 more closely aligned with the Plan-Do-Check-Act cycle, and also means easier integration with other management system standards. To learn more, see ISO 9001:2015 Annex A – What is it used for and why use it?.

Context of the organization – The new revision contains a requirement for the organization to determine which issues (both internal and external) could impact its ability to meet its objectives. In addition, there is a new requirement for the organization to identify interested parties, as well as their needs and expectations. For more information, read: How to identify the context of the organization in ISO 9001:2015.

Risk-based thinking – Further aligning ISO 9001 with other management system standards, there is a new requirement to address risks and opportunities, while preventive actions have been dropped from the requirements in the new version. To learn more about risk-based thinking, check out The Role of Risk Assessment in the QMS.

Deleted requirements – The revised standard was designed to be simpler and more compatible with other ISO standards. To this aim, some requirements present in the previous revision were discarded, including management representative, quality manual, mandatory documents, and preventive actions, among others. To find out more, see Infographic: ISO 9001:2015 vs. 2008 revision – What has changed?.

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What does the new
ISO 9001 look like?

ISO 9001:2015 is divided into 10 sections. Sections 1 through 3 serve as an introduction, while the remaining seven sections define the requirements for the QMS. Following is an explanation of these seven main sections:

Section 4: Context of the organization – discusses basic requirements for a Quality Management System, requirements for determining an organization's internal and external context as it relates to the QMS, and interested parties and their needs and expectations. To learn more, read How to determine interested parties and their requirements according to ISO 9001:2015.

Section 5: Leadership – addresses the requirement for top management to demonstrate leadership during both implementing and maintaining the QMS. This means that top management must be involved in the planning stage, as well as the ongoing maintenance and review of the QMS to ensure continual improvement and customer satisfaction. Find out more: How to comply with new leadership requirements in ISO 9001:2015.

Section 6: Planning – involves setting quality objectives, as well as determining the risks and opportunities as they relate to the company's ability to deliver product and service as intended. To learn more, see How to Write Good Quality Objectives.

Section 7: Resources – defines the requirements for the infrastructure, communication, documented information, and human resources necessary to a successful QMS. Such resources must be provided by the organization if the QMS is to work effectively.

Section 8: Operation – sets the requirements for the organization's key processes, making this section the very core of the ISO 9001 standard. Each process in the section has its own sub clause, beginning with the purchasing process and design and development, all the way to the production/service provision process and release and deployment of product and service.

Section 9: Performance evaluation – describes how to perform monitoring and measurement on the performance of the Quality Management System, with the goal being to show proof of its effectiveness. It also sets the requirements for management review and the internal audit. You can learn more here: Analysis of measuring and monitoring requirements in ISO 9001:2015.

Section 10: Improvement – addresses the requirement for the organization to perform corrective actions according to monitoring and measurement data, in order to continually improve the Quality Management System and correct any nonconformities.

If you would like further information about ISO 9001:2015, check out ISO 9001:2015 revision – List of helpful materials.

Each of the above sections was developed according to the Plan-Do-Check-Act cycle (or PDCA). As its name implies, the PDCA cycle uses the elements of Plan, Do,

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Check, and Act to execute changes to a company's processes to drive process improvement and maintain it over the long term.

PDCA was originally developed by Walter Shewhart, and brought to the mainstream by Edward Deming—both of whom were instrumental in developing modern quality control. The idea is that by following this cycle to implement change in a process, and repeating it over time, the process would benefit from continual improvement. Here's an example we all can relate with: say you decide to go with a new wireless service provider. You may Plan to have continuous service with no dropped calls. When you begin using the service, you enter the Do phase. You may Check the actual performance and realize some calls are dropped. Then, you will Act: will you decide to call customer service and try to fix the issue, go back to your previous wireless carrier, or simply accept that some calls will be dropped?

The benefit of this improvement model is that it is continuous and sustainable, instead of just a single "quick fix." This is why the ISO 9001 standard uses this model: the main goal ISO 9001 is continual improvement to the QMS. To find out more about the PDCA cycle, check out Plan-Do-Check-Act in the ISO 9001 Standard.

Why **ISO 9001** should be seen as a **business management system**

Look further at the requirements of the ISO 9001 standard—you'll realize that there is a lot more to it than just the quality department and its roles and responsibilities. The requirements cover all the activities necessary to provide products and services according to customers' specifications, and to ensure the satisfaction of those customers. Some of the additional requirements include design, requirements control, resource management, process improvement, control of production and service provisions, and purchasing management.

ISO 9001 requirements include everything necessary for managing an organization, and that includes all processes needed to manage resources and other top-level processes. The scope of the Quality Management System must include every part of the business, from sales and planning activities, all the way to delivery and post-delivery. The truth is, some organizations have advanced to a level in which the term "quality" isn't even used. The QMS has simply become the way they do business.

The way ISO 9001 works, organizations are given nearly unlimited leeway in deciding how to meet the requirements. The standard outlines the basic rules of

what must be done, but it does not prescribe how to do it. As an example, ISO 9001 states that a document's current revision status must be recorded, but it does not specify how it must be recorded—you can choose to go by date, or use a revision number, or some other means. Because of this flexibility, the ISO 9001 standard allows you to keep the processes you already have (if they work), and it can become the foundation for your company to apply other standards and build other management systems. This makes it easy for a company to add another system for IT management or environmental management, and share resources among them.

Think of ISO 9001 as a framework you can utilize to help your company become better at everything it does. Using this structure, which is based on continuous improvement, you can begin with what your company already does well, and develop an improved system around your business and its customers. By creating a better system for how your company does business, you will better meet customer requirements and provide better customer service. When you look at it this way, why would you not want to improve the way you do business and keep your customers clamoring for more?

What can ISO 9001 bring to your company?

What ISO 9001 can bring to your business may surprise you. Organizations of all sizes have found tremendous benefits with this standard, including big savings in both costs and efficiency. Here's how your company might benefit:

Improved public image – By showing that you have been professionally certified, you show your customers and the public at large that you utilize a system dedicated to improving customer satisfaction. They will know that you can meet customer requirements and deliver promised results.

Better customer satisfaction – A main focus of ISO is raising the satisfaction of customers by properly determining and achieving customer requirements. And, when you have higher rates of customer satisfaction, you see higher rates of repeat business.

Increased efficiency – A QMS based on ISO 9001 uses a process approach that examines each process within your company, as well as how those processes interact. In this way, it becomes easier to determine where you can make improvements, and where you can combine and save resources.

Better decision making – A successful Quality Management System depends on good decision making based on sound evidence. This allows a company to better use its resources to address problems, improve efficiency, and increase effectiveness.

Make improvement the norm – Because the main goal of ISO 9001 is continual improvement, your company can realize greater and greater savings of resources like time and money. If your company culture is continual improvement, then your employees will naturally focus their talents on making their own processes better.

Engaged workforce – There is no one better suited to discover solutions for improving a process than the employees who spend their days working within that process. When employees are encouraged to improve their processes, rather than just managing them, they become more engaged in the success of the company as a whole.

Easy integration of other management systems – As a basic management system standard, ISO 9001 provides an excellent framework for the implementation of other industry-specific standards. With their common structure and similar requirements, once ISO 9001 is implemented, it's easy to add the required elements of other standards. The basics are already covered, like management review, internal audit, document management, etc. To learn more about how to integrate ISO 9001 with ISO 14001, see Integrating ISO 9001 and ISO 14001.

To find out how ISO 9001 relates to ISO 27001 or ISO 20000, download one of these free whitepapers: ISO 27001 vs. ISO 9001 matrix (PDF) or ISO/IEC 20000-1:2011 vs. ISO 9001:2015 matrix (PDF).

Common myths concerning ISO 9001

ISO 9001 is widely recognized, and has been around for decades. Even so, there is a remarkable amount of misinformation that has persisted. So, how did these myths come to be, and is there any truth to them? Following are the six greatest myths surrounding ISO 9001, and their explanations:

1) ISO 9001 tells us how to do our jobs – I think this is the most common myth. In some companies, people don't seem to understand that ISO 9001 doesn't prescribe the "how" of a process; they simply define the important elements that must be considered during the process. Often, a process owner doesn't see why a particular element must be included in their process, and to make things easier, they are told that ISO 9001 says it has to be done that way. In reality, the standard only offers suggestions of how to incorporate the requirements. It's important that we take care when communicating requirements to those who must apply them.

2) ISO 9001 is a quality department thing – It's often thought that ISO 9001 falls under the responsibility of the quality department, and the quality department alone. This is completely false, as the standard covers every facet of the business, from product and service planning all the way through delivery and post-delivery.

3) ISO 9001 doesn't fit my company – I often hear things like: "ISO 9001 is just for large companies," or "ISO 9001 doesn't apply to service providers." This is simply not true. The requirements prescribed by ISO 9001 were designed to apply to any organization, large or small, in any type of business. The standard offers best practices that any company can use to improve its business processes—no matter what industry it operates in.

4) We have to document everything – This misconception is understandable, because when ISO 9001 was first conceived, the mantra was "Write what you do, and then do what you write." In the early versions of the standard, all aspects had to be documented. However, this has not been the case since the publication of the 2000 version. Now, individual organizations may decide what they need to document in order to comply with the requirements. I've also heard similar statements like: "You have to keep records of everything," and "Procedures have to be overly complicated," but these are also incorrect.

5) ISO 9001 implementation and maintenance cost too much – Of course there is some level of costs involved when implementing ISO 9001, and when monitoring and maintaining the system. But, these costs are more than offset by the benefits achieved through a successful QMS. The goals of ISO 9001 are to ensure increased customer satisfaction, find and correct the root cause of any problem, and continually improve company processes. If done well, the result will be reduced costs due to continual improvements, and increased profits due to happy customers. You can do the math, but your ROI should be considerable.

6) Everything has to be perfect to begin with – Well, if this were the case, then how could you continually improve as mandated by ISO 9001? Company processes must be established and carefully monitored, allowing you to spot any problems and correct them (and apply corrective action to their root problems). That doesn't mean they have to be perfect. It could be that this myth is the root cause of another: "It takes years to implement an ISO 9001 Quality Management System." This is definitely not the case—you can actually start with the processes that already work well in your company, maybe with some minor adjustments, and use these as the foundation of your QMS. As you continue to use your system, it will continually improve.

Of course there are numerous other myths surrounding ISO 9001, but these are probably the most likely to undermine our credibility when trying to explain how ISO 9001 can help our businesses effectively control their processes and improve customer satisfaction. If we can disprove these myths, then maybe we can help more organizations reap the benefits of implementing a QMS based on ISO 9001.

How to get **management** on board

Can you get ISO certification without buy-in from top management? You may be asking yourself this question when deciding if you can implement ISO 9001 in your own company. The answer is yes, it's possible to complete the initial implementation with minimal support from management (some things are required, like management review), but it would be very difficult—maybe impossible—to maintain the QMS without continuing support from management. The initial ISO 9001 certification is relatively easy compared to maintaining the system and the certification. To keep it, you have to show ongoing support, particularly through continual improvement, which is nearly impossible without ongoing support from management.

To get management on board, you have to speak their language: the language of dollars and cents. But, as discussed in Six Key Benefits of ISO 9001 Implementation, it can be difficult to describe the benefits of implementing ISO 9001 in dollars and cents.

To help get buy-in from your top management, use this Project proposal for ISO 9001 implementation.

What are the **milestones** in ISO 9001 implementation?

What does ISO 9001 certification mean, anyway? There are actually two ways to become certified: a company can have its QMS certified against the requirements of ISO 9001, and individuals can become certified to perform audits according to the ISO 9001 requirements. For the purposes of this white paper, we will discuss the steps needed for an organization to set up its Quality Management System and get it certified against ISO 9001.

To have your company certified, a QMS must first be implemented based on the requirements of ISO 9001. Then, you will need to hire an appropriate certification body to perform an audit and certify that your QMS meets the standard requirements.

Beginning with support from top management and identification of customer requirements, you'll need to define your quality policy and quality objectives, and define context of your organization. Together, these documents describe the complete scope of the QMS. In

addition, you'll need to develop the mandatory processes and procedures, and any additional ones needed by your company to effectively construct and deliver its products and services.

There are different methods to creating this documentation: your company may choose to develop these documents internally, or to get assistance from a consultant or by acquiring documentation templates. To take a look at documentation samples, check out this free ISO 9001 downloads page.

After you have put the required processes and procedures into place, you will have to operate the Quality Management System for some time. This allows you to gather the information needed for the steps to follow: auditing and reviewing the system, and becoming certified.

Download this List of questions to ask ISO 9001 Certification Body to help you find the right certification body.

Required steps to complete the implementation and become certified

Once the documentation is completed and implemented, your company will need to perform the following steps to become certified:

Internal audit – Here is where you check your Quality Management System processes. The aim is to make sure that records exist to show that the processes comply, and to discover any problems and flaws that could be hiding.

Management review – Management must conduct a formal review of the QMS processes for effective decision making and the assignment of resources.

Corrective actions – After the internal audit and the management review, you must apply corrective action to the root cause of any problem and document the resolution.

There are two stages in the certification process for companies:

Documentation Review (Stage 1) – Auditors from the certification body will check your documentation to make sure it meets ISO 9001 requirements.

Main Audit (Stage 2) – This is when the auditors review your documents, records, and business practices to see whether your actual activities comply with ISO 9001 and your own documentation.

To learn more about the implementation and certification processes, see this ISO 9001 Implementation Diagram.

Maintaining your QMS once the consultant is gone

Everyone needs help from time to time, from someone more experienced. Many companies choose to hire an ISO 9001 consultant to help with implementing the standard. Let's face it: when you think about creating a Quality Management System and all its documentation by yourself, it can be a bit overwhelming. In addition to creating all the mandatory documentation described earlier, you also have to educate staff, implement the system, and make sure that management is in support of the project along the way. If you are part of a large company, or one with complex products or services, you

will probably have to develop a huge amount of documentation that must be cross-referenced and linked together. Getting help from someone who knows the ins and outs of the standard is appealing.

But remember, that consultant has to leave sometime, and he will take his knowledge and expertise with him. It is crucial that you learn as much as you can during the implementation stage so that you know what to do when you don't have that help any longer.

Conclusion

ISO 9001 has made a big impact all over the world, and its success has paved the way for the adoption of other standards. Because of the confidence that companies and professionals worldwide have in ISO 9001 (See the results of our ISO 9001 survey), it will undoubtedly continue to be an important tool for achieving high levels of quality and customer satisfaction.

The latest version if the ISO 9001 standard offers greater flexibility to companies in their creation of a Quality Management System, making it easier than ever to incorporate the requirements into their daily activities. After all, this is the best and only way that a QMS can be effective and provide the greatest benefits to an organization.

References

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ISO survey

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