Quality Mantra Feb, 2023
A Newsletter of International Certification Services

ISO 9001:2015

Myths regarding ISO 9001 : 2015
By Dr. Sundar Kataria (CMD)

India is very large continent with one of the World's Industrial and Agriculture Heritage. Quality is utmost important and vital of the products and services in the global scenario. Today global world is shrinking of its boundary because of development of effective and fast communication, transportation, innovation, technological and management system. Government of India has been providing and focusing to improve consumer awareness, technical development and quality competitiveness towards enhancement of quality of products and services.

ISO has provided us with many international management systems out of which most modern management system are well harmonized with other countries standards, codes and guidelines and practices that are accepted throughout the globe and recognized by more than 200 countries. The most acceptable and the basic quality management system is ISO 9001:2015 which is used worldwide to ensure the quality of products and services.

Even though ISO 9001 has been around for years and many people know about it but the amount of misinformation that surrounds the standard is surprising. Where do these myths come from and what is the truth about the standard ISO 9001?

Below given are six myths

1. ISO 9001 says we have to do it this way: This is a common standard. You can use it according to your company. This standard identifies the key elements/activities that we need to pay attention to and how they relate to what ISO requirements need to be implemented and maintained.

2. ISO 9001 belongs to quality department only: Many of us think that ISO standards are the sole responsibility of the QA/QC department, but that is not the case. Rather, requirements cover all aspec ts of doing business, from customer requirements to product and service offerings.

A. ISO 9001 does not apply to my business: It is generally believed that this standard is for manufacturers and not for service providers. The standard can be used by companies of all sizes, types and industries, including manufacturing and finance.

B. Everything needs to be documented: There is too much documentation. ISO 9001:2015 requires bare minimum documentation in any form what you do, do what you write is not true but now discretion is left to the organization as what need to be documented to ensure compliance of the product and services. You need not keep records of everything.

C. ISO 9001 is expensive to implement and maintain: You need to incur initial expenses to implement the ISO requirement through external and internal training and some processes are to be monitored and improved management system continuously. The main objective of the ISO 9001 is to help you achieve greater customer satisfaction, eliminate waste, reduce cost and improve ROI.

D. Everything needs to be perfect at the start: The processes have to be adequately monitored so that you can detect problems and non-conformity and apply appropriate correction, corrective action to the root causes of these problems / NCR to improve the management quality system. Hence myth that everything has to be perfect is not true.

Of course, there are other myths about the ISO 9001 standard, but these undermine our credibility for using ISO 9001 as a way to help organizations manage their processes to improve and increase customer satisfaction. Hopefully, resolving these issues will help more companies realize the benefits of implementing a quality management system.

Introduction to QMS By Yogesh Chandekar (AVP - Certification

What is a Quality Management System?

A quality management system which is often referred to as a QMS, is a way of defining how an organization can meet the requirements of its customers and other stakeholders affected by its work. It is a collection of policies, processes, documented procedures, and records. This collection of documentation defines the set of internal rules that will govern how your company creates and delivers your product or service to your customers. The QMS must be tailored to the needs of your company and the product or service you provide. It is designed to be flexible enough for use by many different types of organization, so does not specify what the objectives relating to “quality” or “meeting customer needs ” should be. Instead, it requires organizations to define these objectives themselves and continually improve their process es in order to reach them.

How is ISO 9001 implemented?

Starting with management support and identifying the customer requirements for the QMS, you will need to start with defining your quality policy and quality objectives, which together define the overall scope and implementation of the Quality Management System. Along with these, you will need to create the mandatory and additional processes and procedures necessary for your organization to properly create and deliver your product or service

Implementing a quality management system will help you:

• Assess the overall context of your organization to define who is affected by your work and what they expect from you.

• Put your customers first, making sure you consistently meet their needs and enhance their satisfaction.
Once all of the processes and procedures are in place, you will need to operate the QMS for a period of minimum 3 months. By doing this, you will be able to collect the records necessary to go to the next steps I.e. to audit and review your system and get certified.

What is QMS certification?

QMS (ISO 9001) certification refers to certification of a organization's Quality Management System against the ISO 9001 requirements. ISO 9001 certification for your company involves implementing a QMS based on the ISO 9001 requirements, and then hiring a recognized accredited certification body to audit and approve your QMS after verifying the compliance to the requirements of the ISO 9001 standard. Once your organization is ISO 9001 certified, you will get the certificate with accreditation body and certification body logo that you can use to advertise that your company has met all of the ISO 9001 requirements.

Steps for a Company to get ISO 9001 Certified

For the company QMS to be certified, you need to first finish the implementation. After finishing all your documentation and implementing your processes, your organization also needs to perform these steps to ensure a successful certification:

Internal audit – The internal audit is in place for you to check your QMS processes. The goal is to ensure that records are in place to confirm compliance of the processes and to find problems and weaknesses that would otherwise stay hidden.

Management review – A formal review by your management to evaluate the relevant facts about the management system processes in order to make appropriate decisions and assign resources.

Corrective actions – Following the internal audit and management review, you need to correct the root cause of any identified problems and document how they were resolved.

After registration with certification body, the company certification process is divided into two stages:

Stage One (documentation review) – The auditors from your chosen certification body will check to ensure your documentation meets the requirements of ISO 9001.

Stage Two (main audit) – Here, the certification body auditors will check whether your actual activities are compliant with both ISO 9001 and your own documentation by reviewing documents, records, and company practices.

Benefits of ISO 9001-

The benefits of ISO 9001 cannot be overstated; companies large and small have used this standard to great effect, securing cost savings and additional revenue. Here are just a few of these benefits:

Improve your image and credibility – When customers see that you are certified by a recognized certification body, they will understand that you have implemented a system that is focused on meeting customer requirements and improvement. This improves their trust that you will deliver what you have promised, and it will get you new clients.

Improve customer satisfaction – One of the key principles of the ISO 9001 QMS is the focus on improving customer satisfaction by identifying and meeting customer requirements and needs. By improving satisfaction, you improve repeat customer business.

Fully integrated processes – By using the process approach of ISO 9001, you not only look at the individual processes in your organization, but also at the interactions of those processes. By doing this, you can more easily find areas for improvement and resource savings within your organization.

Use evidence-based decision making – By ensuring that your decisions are based on good evidence, you can better target resources to the best effect to correct problems and improve your organizational efficiency and effectiveness.

Create a culture of continual improvement – With continual improvement as the main output of the QMS, you can attain ever-increasing gains in savings of time, money, and other resources. By making this the culture of your company, you can focus your workforce on improving the processes they are directly responsible for.

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How to Address Risks and Opportunities in ISO 9001:2015

By Ganesh Deherkar (Sr. Manager- Marketing)

When using the ISO 9001:2015 requirements as a basis for your Quality Management System (QMS), you will find that risk-based thinking is an important new concept that has been brought into the forefront of quality planning. Along with this notion that it is important to think about risk, there are also requirements to identify and address risks and opportunities within the Quality Management System, but how do you do this? Here is a bit more about what the standard requires and how you can address these requirements within your QMS.

What do the ISO 9001:2015 requirements actually specify?

The requirements for addressing risks and opportunities are spread throughout the ISO 9001:2015 standard, starting at the beginning in section 4.4.1, where the organization is required to determine the processes needed to address risks and opportunities that are determined. This is reinforced in section 5.1.2,where top management needs to ensure that risks and opportunities that affect product and service conformity are determined and addressed.

The real meat of the requirements for risks and opportunities is in section 6.1 on actions to address risks and opportunities. This section discusses the need to plan the actions needed to address the risks and opportunities, integrate these actions into the QMS, and evaluate the actions for effectiveness. These actions need to be in proportion to the potential impact on product and service conformity, and there are many ways to address risk, from avoiding it to accepting it.

The last mentions of risk and opportunities are in section 9.1.3 that talks about analyzing the information necessary to determine if actions were effective, and section 9.3.2, which specifies that management review will look at the effectiveness of the actions taken to address risks and opportunities. There is also mention that risks and opportunities should be updated when a non-conformity occurs (section 10.2).

How can you address these requirements?

It is important to note that there are no requirements for a formal process to monitor and control risks and opportunities within the Quality Management System. Just like risk-based thinking, there is not a requirement for full risk management, only the identification of the risks and opportunities and decisions on what action to take. This does not even need to be maintained as documented information within the QMS.

As with any new requirements for ISO 9001:2015, it is a good practice to look at what you already do within your organization to see if you address these requirements with your current business practices. For instance, many companies have business planning processes that look at the risks to the business and the opportunities that could be present, such as the use of a SWOT analysis (strengths, weaknesses, opportunities, and threats).

The use of a SWOT analysis in business planning will also include making plans to address the risks and opportunities identified, which is also required by the ISO 9001:2015 standard requirements. For instance, if you identify a risk that a key component in your product or service will become obsolete, you can make the plans necessary to find a replacement before your customers are impacted by your product becoming unavailable.

If you already do this as part of your business capture strategy, then you are already meeting the requirements of the ISO 9001:2015 standards; if not, then this is certainly an industry best practice that you could be adopt. Remember, the format of this identification is not mandated, so you can look at these risks and opportunities in any fashion you wish.

Why look at risks and opportunities ?

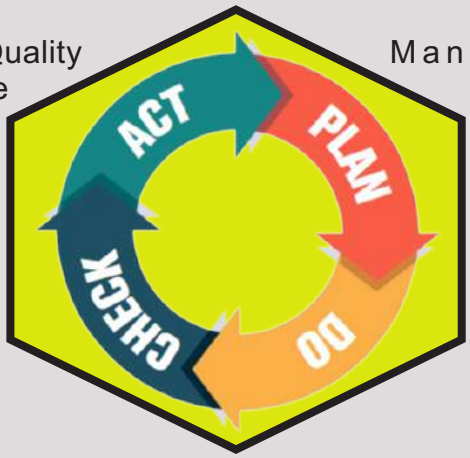
As has been said before, the ISO 9001 standard is intended to be a set of requirements that represent the good practices that form the basis of a Quality Management System, and companies that want to survive will be assessing and addressing risks and opportunities to their businesses as a standard course of action. In order for a business to thrive, you need to identify in some manner what risks you have and how they can affect you.

However, as always, it is important that you find the best way for your organization to do this activity to address your risks and opportunities. This can be as simple as brainstorming for your SWOT analysis and then deciding if you need to do anything about the risks that are identified. This process is there to benefit your business, so do not take extremely expensive steps to implement this system if it is not required for you.

Always remember, a Quality Management System is there to benefit your business, not to cost you excessive amounts of money to run. So, always do what is best for your business.

PDCA Cycle by
Aman Vishwakarma (Asst. Manager - Marketing

PLAN DO CHECK ACT CYCLE



What is the best way to view the ISO 9001 Quality Man agement System requirements in order to make the individual processes within your system more compatible with each other? Each individual process can be improved by applying a Plan-Do-Check-Act approach, but the overall system can also benefit by this philosophy. By looking at the separate processes as being linked in one large cycle for improvement, you can help focus the improvement of the individual processes toward one greater good for the company.

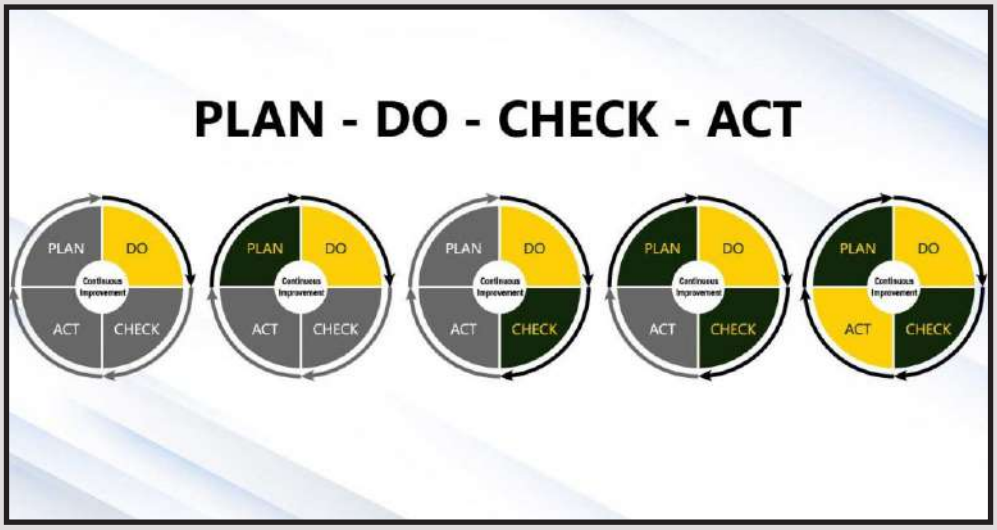
Where does Plan-Do-Check-Act come from?

Plan-Do-Check-Act (also called “PDCA”) is a cycle that was originated by Walter Shewhart and made popular by Edward Deming – two of the fathers of modern quality control. This concept is a cycle for implementing change which, when followed and repeated, would lead to repeated improvements in the process it was applied to. An example that we might all relate to would be when you choose a wireless carrier: you Plan to have no problems with dropped calls; the Do phase is when you start using the phone service; the Check phase is when you monitor the real performance and get some dropped calls; and the Act phase is when you decide what to do – e.g., accept the number of dropped calls, call the provider to try to correct the situation, or change wireless carrier.

This is a model for improvement that is sustained, rather than just a one-time quick fix, and it is for this reason that it is applied to the ISO 9001 standard. The ISO 9001 standard has, as a main goal, the continual improvement of the Quality Management System.

How Plan-Do-Check-Act is found in the ISO 9001 Standard Requirements

In the introduction to ISO 9001, there is an explanation of the Process Approach and how important this is to implementing a Quality Management System that is compliant with the ISO 9001 requirements. In addition to this, there is a note about the methodology know as "Plan-Do-Check-Act" being applied to all processes. It then shows a graphic, which shows a very rough overview of how the standard requirements fit within a PDCA cycle.



Plan – Planning is one of the biggest parts of the QMS and starts with understanding the context of the organization and the needs of parties interested in the QMS, which is then used to define the scope of the QMS and the QMS processes. This is followed by the commitment of leadership in the company to drive the organization to a customer focus by defining the organizational roles and responsibilities and by establishing a quality policy to give the overall QMS a focus. The next level of planning is to identify and address risks and opportunities of the QMS, including setting and planning for quality objectives and changes to support continual improvement. The final level of planning is to identify and implement the support structure to allow you to carry out your plans. This includes resources, identifying competence, awareness, communication and to set the processes for creation and control of documented information.

Do – Planning is useless unless the plan is carried out. Controls need to be identified for the QMS operations, product or service requirements need to be identified, designs developed, controls placed on externally provided processes, products and services. The process of producing the product or service needs to be carried out with control of product and service release, any non-conforming products or services need to be addressed. In short, the activities of creating and providing products or services to the customers need to be done.

Check – There are several requirements in the standard to check the processes of the Quality Management system to ensure they are functioning properly as they have been planned. There is a need to monitor, measure, analyze and evaluate the products or services to ensure they meet requirements, the processes used are adequate and effective, and customer satisfaction is being met. Internal Audit of the processes is the key way to assess the effectiveness of the system. Further is the Management Review process, which reviews and assesses all of the monitored data to make changes and plans to address the issues.

Act – Action in this case involves the actions needed to address any issues found in the check step. Improvement is the overall heading for these action steps with the activities of addressing nonconformity and Corrective Actions to eliminate the causes of actual or potential non conformities as the first step in acting to improve the system.

As stated, this cycle starts again to ensure there are plans in place for further improvement. Findings during the Internal Audit in the "Check" phase may have led to corrective actions from the "Act" phase, which in turn will require changes in planning to meet the updated requirements in the next "Do" phase. The Management Review looks at the outcomes of Internal Audit, Corrective Actions and outputs resource plans to support any changes. Resources are assessed and increased, decreased or re-assigned as the business needs dictate. This leads into another round of Doing, and the cycle continues.

An example would be if your company planned to reduce scrap by 5% by making certain changes to a process, the changes were made and the process ran, checking of the process showed that you reduced the amount of scrap by 3%, and you acted to make further changes to improve. The next planning for this process might be to make further changes and reduce the scrap by a further 4% in the following year.

Use PDCA to focus your QMS toward improvement

The goal of a QMS is to work toward improvement for the company, because only through improvement will a company be able to compete in industries that are growing ever more competitive. By using the PDCA cycle you will help to focus the processes and objectives of the QMS toward this desired improvement, leading to savings in time and money that can be used to improve further. With improvement as the goal of the QMS, the betterment and persistence of the business is more certain.

Training Calendar

Course Title	Start Date	End Date	Fees	Duration	Class Type
Lead Auditor Training on QMS	6th Feb 2023	10th Feb 2023	INR 15,000 + 18% GST	10am to 5.30pm	Online
Internal Auditor on QMS	6th Feb 2023	7th Feb 2023	INR 40,000+18% Gst GST	10am to 5.30pm	Offiline /Mazgaonne
First Aid	3rd Feb 2023	Feb 2023	INR 8,000 + 18% GST	10am to 5.30pm	Online
Road Saftey	4th Feb 2023	Feb-23	INR 9,000+ 18% GST	10am to 5.30pm	Online

Stress Buster Zone  On ISO 9001:2018

1.In ISO 9001:2015 records and documents are now called documented information.

- False
- True

2.Person or group of people who directs and controls an organization at the highest level are called:

- Top Management
- Management Representative

3.Who is responsible to establish, implement and maintain a quality policy?

- Top Management
- Quality Director

4.The organization shall conduct the Management Review at least once a year.

- FALSE
- TRUE

5.Intentions and direction of an organization as formally expressed by its top management is called:

- Policy
- Vision

6.Which of the following is NOT the way to deal with the nonconforming outputs?

- Correction
- Preventive Actions

7.The effect of uncertainty is called the:

- Probability
- Risk

8.Six mandatory procedures are required in ISO 9001:2015.

- FALSE
- TRUE

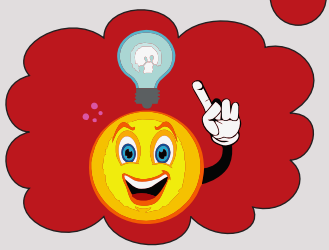
9.The context of the organization need to be maintained as documented information.

- TRUE
- FALSE

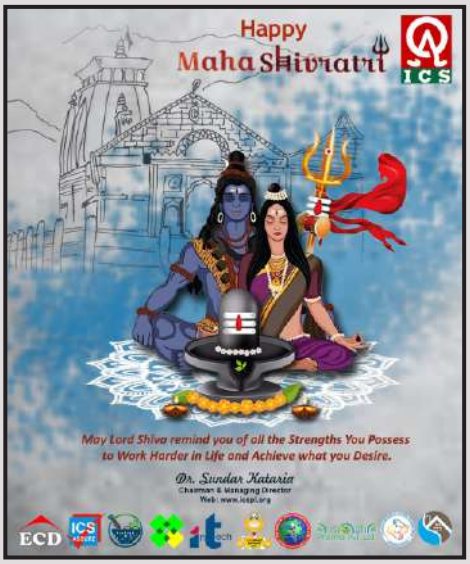
10."Action to eliminate the cause of a nonconformity and to prevent recurrence" is called a:

- Corrective Action
- Correction

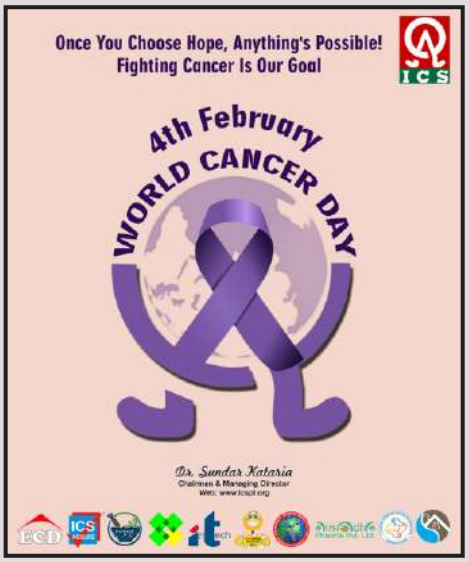
Answers



1.True, 2.Top Management, 3.Top Management, 4.False, 5.Policy
6.Preventive Actions, 7.Risk, 8.True, 9.True, 10.Corrective Action



Feb-2023 Festival



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