

Importance of ISO 9000

ISO 9000 represents a set of standards that focuses on process improvement to achieve error-free results.

ISO 9000 has been globally adopted by 900,000 organizations located in 170 countries since 2000, according to David Levine, professor of business administration in the Haas School of Business at University of California, Berkeley. This certification has opened doors to new business opportunities from companies that only accept contract agreements with organizations that have compatible quality systems. In addition, ISO 9000 has brought internal clarity about how well a company performs in delivering quality product, resulting in increased customer satisfaction.

1. Description

- ISO 9000 forms a set of standards, issued by the International Organization for Standardization (ISO), describing a quality management philosophy. High quality represents an error-free environment. The effort of achieving zero defects starts with documenting all the internal processes of the company. The staff commits to closely following the instructions listed in the process documents. Close monitoring records how well the process is working. When one of the tasks generates results that deviate from expectation, the company reviews and improves the process or retrains the operator.

Context

- The International Organization for Standardization has generated an extensive portfolio of global guidelines, including more than 18,000 standards. Since its inception in 1947, ISO has encouraged countries to participate in defining the international standards by collecting opinions and recommendations from each nation. Today, 163 nations team up with ISO and appoint one representative per country to participate in these discussions.

History

- ISO 9000 follows the steps of an older standard begun by the British government, BS 5750, that dates back to World War II. BS 5750 saved the lives of factory workers by imposing rigorous quality requirements on munitions to avoid explosions in military bomb factories. The United Kingdom recommended translating BS 5750 into standards that would be relevant to non-military applications. ISO developed several versions of the documents and issued ISO 9000 in 2000. The latest version is ISO 2001:2008.

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- A study of ISO 9000 deployment from the University of California Los Angeles showed that ISO 9000 has been exponentially adopted by hundreds of thousands of companies in less than 10 years, from 1992 to 2002. Starting with the buy-in from the United Kingdom, the interest spread to the United States, Australia and New Zealand. Today, the 900,000 ISO-certified companies include 170 countries in Europe, Asia, Africa and the Americas.

Impact

- ISO 9000 positively impacts the internal functions of an organization by tightening processes and ensuring that all personnel is trained appropriately. Upper management also states specific quality goals that tend to focus staff's energy onto flawless execution. This top down clarity of corporate direction and the specific job or task instructions from the process documentation make the work environment more predictable and boost staff morale. Companies often request ISO certification from their suppliers and business partners before a partnership agreement can be signed. Hence, new doors of business opportunities typically follow an ISO 9001:2008 certification.
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A Brief Intro to the 20 Elements of ISO-9000:1994

While this is not a copy of the standard, it is a brief synopsis of the elements and offers an idea of the requirements.

4.1: Management Responsibility
Top Management is required to:

1. develop a Quality Policy reflecting the organization's attitude to quality and ensure it is communicated throughout the organization.
2. allocate appropriate resources and trained personnel to perform the work.
3. appoint a management representative to monitor the Quality System.
4. conduct regular management reviews to ensure the health of the quality system .

4.2: Quality System
The system must:

1. be fully documented within the framework of ISO 9000.
2. satisfy customer's requirements and specifications.
3. be adapted to your organization.
4. define how quality requirements will be met.
5. demonstrate thorough planning to meet customer requirements.

4.3: Contract Review

1. Sales must review the orders and contracts with the customer.
2. Any change must be reviewed and agreed to with the customer.

4.4: Design Control
All phases of product or service design (engineering) must be controlled and conducted by qualified personnel. (This pertains to ISO-9001 only.)

4.5: Document and Data Control

1. All documents and data used must be controlled and authorized.
2. Obsolete documents must be removed form circulation; latest issues must be located at appropriate areas throughout the facility and available at the workplace.

3. Changes must be recorded and released in a controlled manner.

4.6: Purchasing

1. Purchasing information must be complete and accurate.
2. Suppliers must be qualified and selected based on demonstrated quality.
3. Suppliers must be monitored continuously.

4.7: Control of Customer Supplied Product
If and when customers supply the materials for their products, you must ensure that:

1. you report to the customers any discrepancy or damage to their products.
2. their products can be identified easily.
3. their products are handled and stored accordingly.

4.8: Identification and Traceability
Products must be identified at all times and through all phases of production.

4.9: Process Control
You are required to have a complete process, with appropriate written procedures, to perform and monitor all production activities, which affect quality.

4.10: Inspection
You are required to have documented verifications at all critical stages of your process:

1. Receiving of raw material.
2. Work in process.
3. Final inspection.

4.11: Calibration
All inspection and measuring equipment (Gauges, thermometers, scales , test software...) must be controlled and maintained in calibration. You are required to:

1. provide unique identification and list of all inspection and measuring equipment.
2. determine the required accuracy.
3. protect and maintain the equipment to ensure continuing accuracy.
4. calibrate each instrument on a pre-determined cycle to established procedures.

4.12: Inspection and Test Status
The test status of all product must be identified through all phases of production. The test status indicates whether the product has passed or failed inspection.

4.13: Control of Nonconforming Product
Any nonconforming product must be properly identified and segregated (if practical) with a documented disposition.

4.14: Corrective and Preventive Action
You are required to have a formal process to correct and prevent problems from occurring. The

process will insure that:

1. root cause is investigated
2. corrective and/or preventive action is taken
3. the effectiveness of corrective and/or preventive is verified

4.15: Handling, Storage, Packaging, Preservation and Delivery
You are required to have documented procedures for:

1. Handling
2. Storage
3. Packaging
4. Preservation
5. Delivery

4.16: Control of Quality Records
Records which demonstrate compliance to procedures and ISO-9000 must be:

1. identified
2. legible
3. accurate
4. filed and indexed properly
5. easily retrievable
6. retained for a specified period of time

4.17: Internal Quality Audits
You are required to conduct formal internal audits to examine all activities affecting quality, and evaluate their compliance to:

1. documented procedures.
2. ISO 9000 requirements.

4.18: Training
You are required to:

1. identify training needs.
2. provide appropriate training.
3. document training activities.
4. ensure only trained people carry activities affecting product quality.

4.19: Servicing
If you provide "servicing" as part of the contract, you are required to control:

1. the design and use of the service equipment.
2. use trained and qualified personnel.
3. ensure product and parts availability.
4. document working procedures and methods.

4.20: Statistical Techniques

Any data analysis, sampling methods, and SPC used must be based on established procedures and sound statistical techniques.

For a complete copy of the Standard, please visit the American Society of Quality web site (www.asq.org) or call 1-800-248-1946 .

1) Control of Documents Procedure:-

This is one of the “Mandatory Procedure” requires by the ISO 9001. Any documents required by the ISO 9001 system must be controlled. Documents include:

- Internal documents (like Quality Policy, Quality Objective, Quality Manual, Quality Procedure, Work Instruction, BOM, Inspection Standard and etc)
- External documents (like Law Book related to organization, Customer Drawing, Customer Specification Requirement and etc).
- Records, in ISO 9001 system, Quality Records and Forms (like Inspection record, Production Record and etc) are a special type of document, and the control must follow the Clause 4.2.4 “Control of Records”

2) Control of Records Procedure:-

Records are generated to provide evidence of implementation, monitoring and control of Quality Management System processes. The control method must include:

- To ensure identification of record, in common practice, we will assign a form number to identify it.
- To ensure the storage methods able to prevent damage, lost and able to retrieved by other
- To ensure the retention of records are identify clearly.
- To ensure the disposition of records are identify clearly.
- To ensure records are remain legible to other.

3) Internal Audit Procedure

Internal audits carried out at planned intervals to ensure the maintenance, improvement and integrity of QMS and its processes.

4) Control of Non-conforming Product Procedure

If any Nonconformity found during the internal audit, the management of the organization is responsible to ensure any necessary corrections and corrective actions are taken without undue delay to eliminate the nonconformities and their causes. This ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

5) Corrective Action Procedure

ISO 9001 requires organization to take action to eliminate the causes of nonconformities in order to prevent recurrence. The corrective actions taken must be able to address the nonconforming root cause.

- The organization must establish a procedure to define:
- Reviewing the nonconformities including customer complaints
- To determine the causes of the nonconformities
- Determining and implementing necessary action needed to correct the nonconformities.
- To review the action taken and effectiveness of the actions to ensure that nonconformities do not recur.
- Record result of correction action

6) Preventive action Procedure

ISO 9001 requires organization to take action to eliminate the causes of potential nonconformities in order to prevent their occurrence. The preventive actions taken must be able to address the potential problems.

- The organization must establish a procedure to define:
- Reviewing the potential nonconformities and their causes
- Determining and implementing necessary action needed to prevent occurrence of nonconformities.
- To review the action taken and effectiveness of the actions.
- Record result of preventive action

The Benefits of ISO-9000

There has been so much written about the benefits of having ISO-9000 registration, there isn't enough space on this website to repeat it all. We will attempt to list some of the basic benefits here.

1. ISO-9000 forces an organization to **focus on "how they do business"**. Each procedure and work instruction must be documented and thus, becomes the springboard for Continuous Improvement.
2. **Documented processes** are the basis for repetition and help eliminate variation within the process. As variation is eliminated, efficiency improves. As efficiency improves, the cost of quality is reduced.
3. With the development of solid **Corrective and Preventative** measures, permanent, company-wide solutions to quality problems are found.
4. **Employee morale** is increased as they are asked to take control of their processes and document their work processes.
5. **Customer satisfaction**, and more importantly customer loyalty, grows. As a company transforms from a reactive organization to a pro-active, preventative organization, it becomes a company people want to do business with.
6. **Reduced problems** resulting from increased employee participation, involvement, awareness and systematic employee training.
7. **Better products and services** result from Continuous Improvement processes.
8. Fosters the understanding that **quality**, in and of itself, is not limited to a quality department but is everyone's responsibility.
9. **Improved profit levels** result as productivity improves and rework costs are reduced.
10. **Improved communications** both internally and externally which improves quality, efficiency, on time delivery and customer/supplier relations.

Why is ISO 9000 important?

The importance of ISO 9000 is the importance of quality. Many companies offer products and services, but it is those companies who put out the best products and services efficiently that succeed. With ISO 9000, an organization can identify the root of the problem, and therefore find a solution. By improving efficiency, profit can be maximized.

As a broad range of companies implement the ISO 9000 standards, a supply chain with integrity is created. Each company that participates in the process of developing, manufacturing, and marketing a product knows that it is part of internationally known, reliable system.

Not only do businesses recognize the importance of the ISO 9000, but also the customer realizes the importance of quality. And because the consumer is most important to a company, ISO 9000 makes the customer its focus.

What are the ISO 9000 Principles?

1. A Customer Focus

As stated before, the customer is the primary focus of a business. By understanding and responding to the needs of customers, an organization can correctly targeting key demographics and therefore increase revenue by delivering the products and services that the customer is looking for. With knowledge of customer needs, resources can be allocated appropriately and efficiently. Most importantly, a business's dedication will be recognized by the customer, creating customer loyalty. And customer loyalty is return business.

2. Good Leadership

A team of good leaders will establish unity and direction quickly in a business environment. Their goal is to motivate everyone working on the project, and successful leaders will minimize miscommunication within and between departments. Their role is intimately intertwined with the next ISO 9000 principle.

3. Involvement of people

The inclusion of everyone on a business team is critical to its success. Involvement of substance will lead to a personal investment in a project and in turn create motivated, committed workers. These people will tend towards innovation and creativity, and utilize their full abilities to complete a project. If people have a vested interest in performance, they will be eager to participate in the continual improvement that ISO 900 facilitates.

4. Process approach to quality management

The best results are achieved when activities and resources are managed together. This process approach to quality management can lower costs through the effective use of resources, personnel, and time. If a process is controlled as a whole, management can focus on goals that are important to the big picture, and prioritize objectives to maximize effectiveness.

5. Management system approach

Combining management groups may seem like a dangerous clash of titans, but if done correctly can result in an efficient and effective management system. If leaders are dedicated to the goals of an organization, they will aid each other to achieve improved productivity. Some results include integration and alignment of key processes. Additionally, interested parties will recognize the consistency, effectiveness, and efficiency that come with a management system. Both suppliers and customers will gain confidence in a business's abilities.

6. Continual Improvement

The importance of this principle is paramount, and should be a permanent objective of every organization. Through increased performance, a company can increase profits and gain an advantage over competitors. If a whole business is dedicated to continual improvement, improvement activities will be aligned, leading to faster and more efficient development.

Ready for improvement and change, businesses will have the flexibility to react quickly to new opportunities.

7. Factual approach to decision making

Effective decisions are based on the analysis and interpretation of information and data. By making informed decisions, an organization will be more likely to make the right decision. As companies make this a habit, they will be able to demonstrate the effectiveness of past decisions. This will put confidence in current and future decisions.

8. Supplier relationships

It is important to establish a mutually beneficial supplier relationship; such a relationship creates value for both parties. A supplier that recognizes a mutually beneficial relationship will be quick to react when a business needs to respond to customer needs or market changes. Through close contact and interaction with a supplier, both organizations will be able to optimize resources and costs.

What is ISO 9000?

Quality is something every company strives for and is often times very difficult to achieve. Complications concerning efficiency and quality present themselves everyday in business, whether an important document cannot be found or a consumer finds a product not up to their expectations. How can a company increase the quality of its products and services? The answer is ISO 9000.

As standards go, ISO 9000 is one of the most widely recognized in the world. ISO 9000 is a quality management standard that presents guidelines intended to increase business efficiency and customer satisfaction. The goal of ISO 9000 is to embed a quality management system within an organization, increasing productivity, reducing unnecessary costs, and ensuring quality of processes and products.

ISO 9001:2008 is applicable to businesses and organizations from every sector. The process oriented approach makes the standard applicable to service organizations as well. Its general guidelines allow for the flexibility needed for today's diverse business world.