QUAD THRO STAND

A solid strategy for successfully implementing ISO 9001 by Raunak Gupta

Various quality gurus, researchers and professionals have defined quality by the different ways they have experienced it. However, most of them have defined quality in terms of one or a combination of the following:

+ **Quality of design—**the salient features for making any product functionally effective are included by the designer in the design stage itself.
+ **Quality of conformance—**the manufacturing of any product is done in such a way that it conforms with the designer's specifications.
+ **Quality of performance—**the product is performing satisfactorily and meets customer expectations up to the defined life.

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Just the Facts

The ISO 9000 series of standards has evolved significantly since its inception in 1987 to stay on top of the quality needs of the market.

The key benefit of ISO 9001 is developing and implementing standard procedures for every process in an organization. This leads to better resource management, chances for continuous improvement, and maintaining product and service uniformity while delivering the same to customers over time.

The author lays out a comprehensive, step-by-step strategy for successfully implementing ISO 9001.

To achieve the desired parameters or results in a particular product according to the designer's specifications, the processes involved must be operated through well-defined procedures that comply with the designer's specifications. This requires developing standard operating procedures for completing a definite task.

The ISO 9000 series of standards was developed in 1987 by the International Organization for Standardization (ISO) to maintain a culture of standard operating procedures for delivering quality products. The series aimed to inculcate the seed of continuous improvement in the work environment while considering market globalization and international standards requirements.

"Standards are made to keep an eye on fulfilling customer demands through conformance."

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There are five parts that make up the ISO 9000 series: ISO 9000, ISO 9001, ISO 9002, ISO 9003 and ISO 9004.[1] ISO 9000 and ISO 9004 provide guidelines for establishing, certifying to and sustaining one of the certifiable quality management standards. These include:

ISO 9001—a model for quality assurance in design, development, production, installation and servicing.

ISO 9002—a model for quality assurance in production, installation and servicing.

ISO 9003—a model for quality assurance in final inspection and testing.

Organizations may apply for certification to any of these three standards based on their needs and market focus. Certification means an organization is following the standard practices in its particular business area to meet the established specifications by designers, customers and other regulators.

All ISO standards are based on seven quality management principles: customer focus, leadership, engagement of people, process approach, improvement, evidence-based decision making and relationship management.[2]

ISO revises the ISO 9000 series of standards every seven years and allows organizations three years to transition from the old version to the new one after the release of the revised standard. After 1987, the ISO 9000 series of standards was revised in 1994, 2000, 2008 and 2015. These revisions have led to changes in the standards according to the quality needs of the market.

1987

In 1987, certification to ISO 9001, ISO 9002 and ISO 9003 required fulfilling requirements related to 20 elements, 19 elements and 13 elements, respectively, as defined in the standards. These elements are shown in Online Table 1, which can be found on this article's webpage at qualityprogress.com.

1994

There was no major change to the 1994 version of the standard. However, much emphasis was placed on preventive actions instead of final product inspection, leading to conformance with the procedures as defined in the standards.

2000

The 2000 version of the standard was changed significantly. The first major change was the merger of ISO 9001, ISO 9002 and ISO 9003 into one standard—ISO 9001. This meant organizations needed to apply for ISO 9001:2000 certification.

The second major change was the standard transitioned from 20 elements to eight sections:

1. Scope.
2. Normative reference.
3. Terms and definitions.
4. Quality management system (QMS).
5. Management responsibility.
6. Resource management.
7. Product realization.
8. Measurement, analysis and improvement.[3]

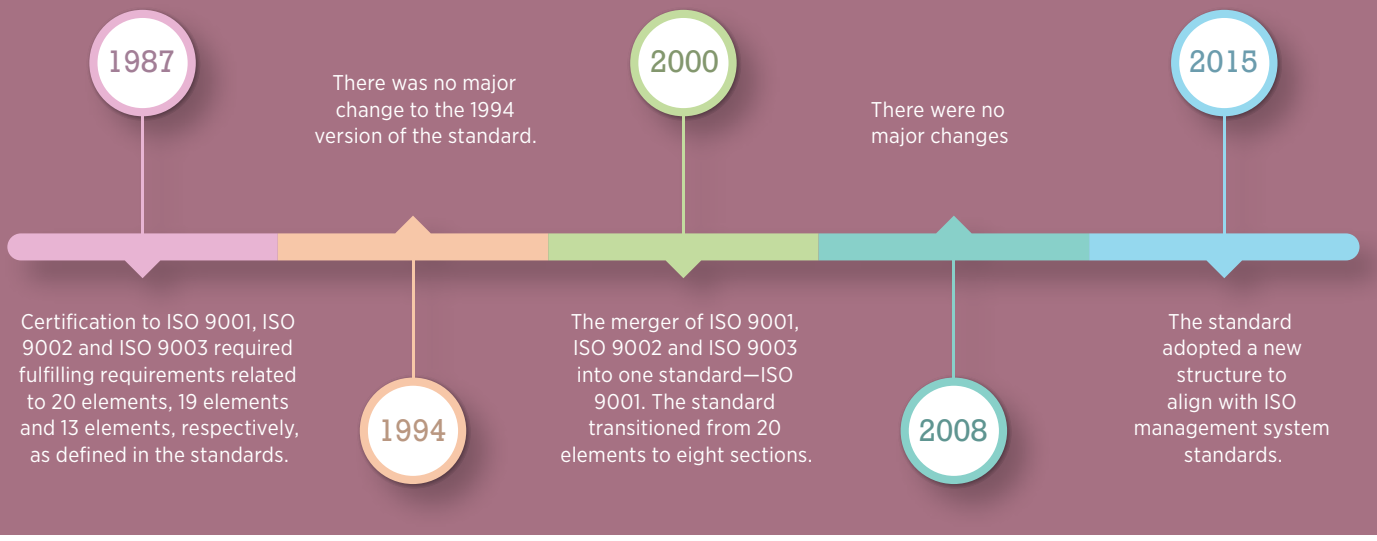
The first three sections related to general information and the rest to implementing the standard.

The standard's structure was process-oriented and worked on the plan-do-check-act cycle. Importance was given to the customer, measurable objectives, continual improvement and training effectiveness.

2008

There were no major changes in the 2008 version in terms of the standard's eight sections. Several clarifications were made in different clauses, however, such as an emphasis on process approach, intermediate products, documentation, management representation, human resources, ergonomics (work environment), design and development, customer-related processes and satisfaction.[4]

Some changes in the 2008 version were implemented to maintain consistency with *ISO 14001:2004—Environmental management systems—Requirements with guidance for use*.



2015

This is the latest version of the standard, released in September 2015. It adopted a new structure to align with ISO management system standards. It consists of 10 sections, compared to the eight sections of the 2008 version. The first three sections are the same as the 2008 version, but the last five sections of the 2008 version were replaced by seven new sections:

Section four: Context of the organization. Requires organizations to determine, monitor and review external and internal issues and relevant interested parties, establish a quality management system (QMS scope and determine a high-level process map (suppliers, inputs, process, outputs and customers).

Section five: Leadership. Requires top management's commitment and accountability for QMS effectiveness in alignment with the organization's context. It also includes dedication to the customer, services and products, quality policy, and defining roles and responsibilities.

Section six: Planning. Addresses the risks and opportunities associated with the processes. It also includes planning for achieving organizational objectives.

Section seven: Support. Requires managing various resources such as human resources, infrastructure, the work-related environment, measuring instruments, and training and awareness programs to perform the task competently.

Section eight: Operation. Focuses on product and service design and development, requirement determination, operational planning and control. It also includes preservation, post-delivery activities and control of nonconformances.

Section nine: Performance evaluation. Involves monitoring and measuring for the analysis and evaluation of products and services for customer satisfaction, management review and internal audits.

Section 10: Improvement. Requires corrective actions for nonconformities and continuous improvement activities related to the products and processes.[5]

In addition to these changes, there also were various changes in the terminology, such as "products and services" instead of "products," "external provider" instead of "supplier" and "environment for the operation of processes" instead of "work environment." ISO 9001:2015 also emphasizes knowledge sharing through training and communication. The various elements of the 2015 version are presented in Online Table 2.

The numbers game

Since its inception in 1987, the popularity of ISO 9001 QMSs has grown around the world among various sectors, including basic and fabricated metal, electrical and optical equipment, construction, machinery and equipment, rubber and plastic products, engineering services and many more.

Figure 1 (p. 37) shows the number of ISO 9001-certified organizations around the world at four-year intervals starting in 1993. It clearly shows that the number of ISO-certified organizations has increased year over year. There was a slight decrease in the number of certifications after 2009, however, due to a change in the mechanism of data provided by the various data providers.[6]

Figure 2 shows the number of ISO 9001-certified organizations in various industrial sectors in 2017 that had more than 30,000 certifications worldwide.[7,8]

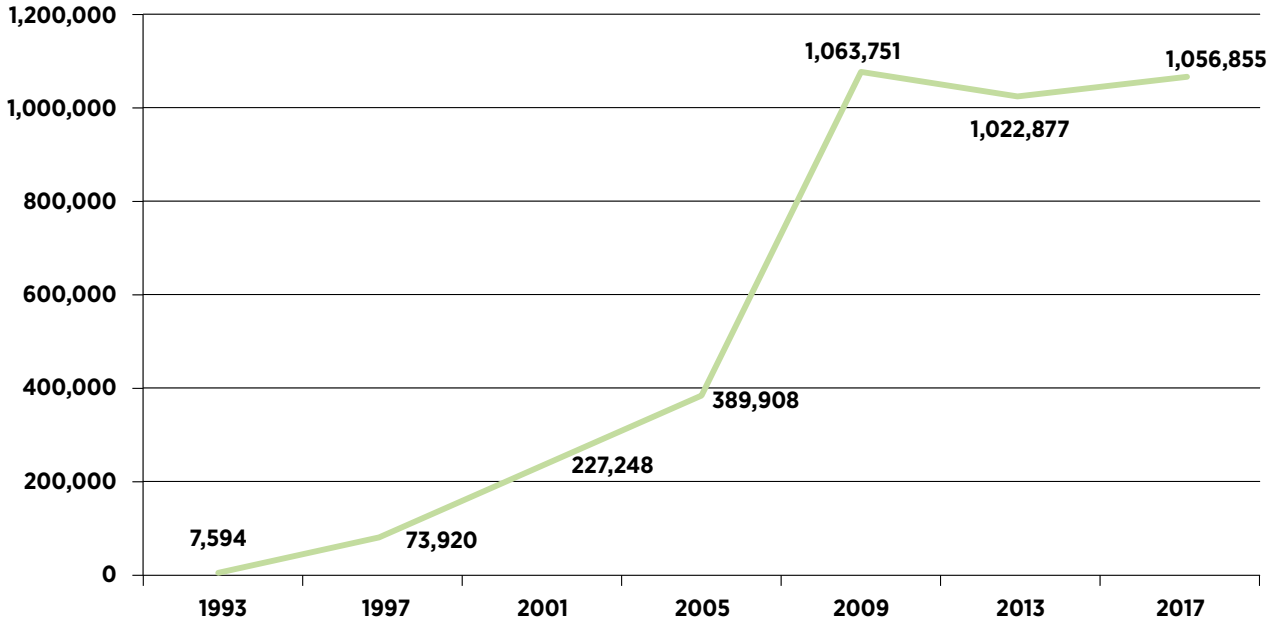
Benefits and limitations

Other than several general benefits of ISO 9001, the key benefit lies in developing and implementing standard procedures for each and every process throughout the organization. This leads to better resource management, increased chances for continuous improvement, and maintaining product and service uniformity while delivering the same to customers over time.

Conversely, there are a few factors that can limit ISO 9001 implementation, including an overemphasis on documentation and a huge financial investment to implement and certify to

FIGURE 1

Number of ISO 9001-certified organizations: 1993–2017



the standard. When organizations focus too much on developing the documents only on the basis of the present mechanism, they can lose sight of the improvement side of the mechanism. Therefore, management and other personnel involved in developing and implementing the standard must have a balanced approach between the documentation and improvement sides of the standard. This balanced approach can be maintained by prioritizing customer satisfaction and employee empowerment.

Implementation strategy

Implementing and certifying to ISO 9001 requires going through three major steps: preparation, implementation and certification.

All the steps required to prepare for and implement ISO 9001 require the involvement of all employees and management. The basic philosophy of ISO 9001 lies in the phrase, "Do what you say and say what you do." The different activities within each of the earlier-mentioned steps are:

Preparation steps

1. Commit. Top management must be committed to instilling a culture of quality management in the organization, and the same must be reflected through the organization's quality policy.
2. Appoint an implementation committee consisting of at least one member from each subdepartment in the organization, such as design, production, quality, maintenance and HR. In total, the committee should have five to six members. The committee must be presided over by a coordinator, who will serve as the management representative and be responsible for successfully implementing the standard.
3. Conduct awareness sessions on the benefits of ISO 9001 for employees, customers, management and the organization.
4. Compare the organization's existing work culture with the one required by ISO 9001. Thereafter, develop an action plan that includes the activities that must be done to achieve that culture. The action plan also must include details such as the responsibilities and timeline for the activities.
5. Develop an organizational structure for implementing ISO 9001.
6. Develop QMS documentation. This is the most important part of establishing ISO 9001 in the organization. It reflects the organization's work culture. The documentation can be

prepared in four levels: quality manual, quality procedures, work instructions and quality records. Each level, along with the respective authority and purpose, is shown in Figure 3.

7. Maintain all the organization's resources in line with the developed QMS documents.

Implementation steps

1. Implement the documented QMS in the organization.
2. Form an internal quality audit team consisting of three to four members and headed by the lead auditor. Team members should be well trained in quality auditing. The team is responsible for conducting regular internal quality audits.
3. Continuously monitor the developed and implemented QMS for five to six months per the prepared guidelines in the documents until the system has been established completely.
4. Conduct an audit. After establishing the QMS, the internal quality audit team should conduct an audit to check for any deviations in the system before proceeding to the next steps.

Certification steps

1. The organization can certify its ISO 9001 QMS by submitting an application along with the necessary documents to any nationally recognized and accredited certification body.
2. The certification body will conduct an adequacy audit to ensure the QMS documentation meets ISO 9001 requirements.
3. After the adequacy audit, the certification body will perform a compliance audit at the organization. This is done to determine the extent to which the QMS documentation has been implemented in the organization.
4. Based on a satisfactory report by the auditor (appointed by the certification body), the certification body will issue ISO 9001 certification to the organization.

The certification remains valid for three years. During that time, the certification body will conduct quality audits at regular intervals to verify compliance with the issued QMS.

FIGURE 2

Number of ISO 9001-certified organizations: industrial sectors – 2017

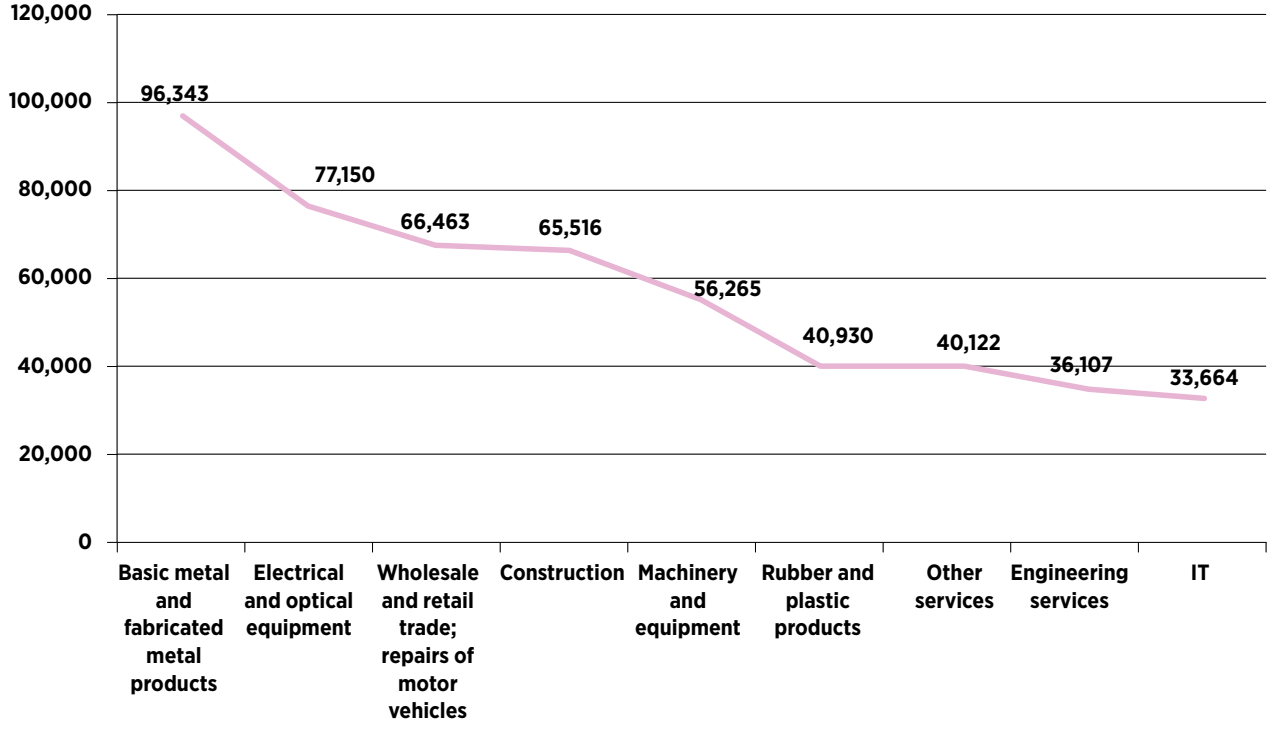


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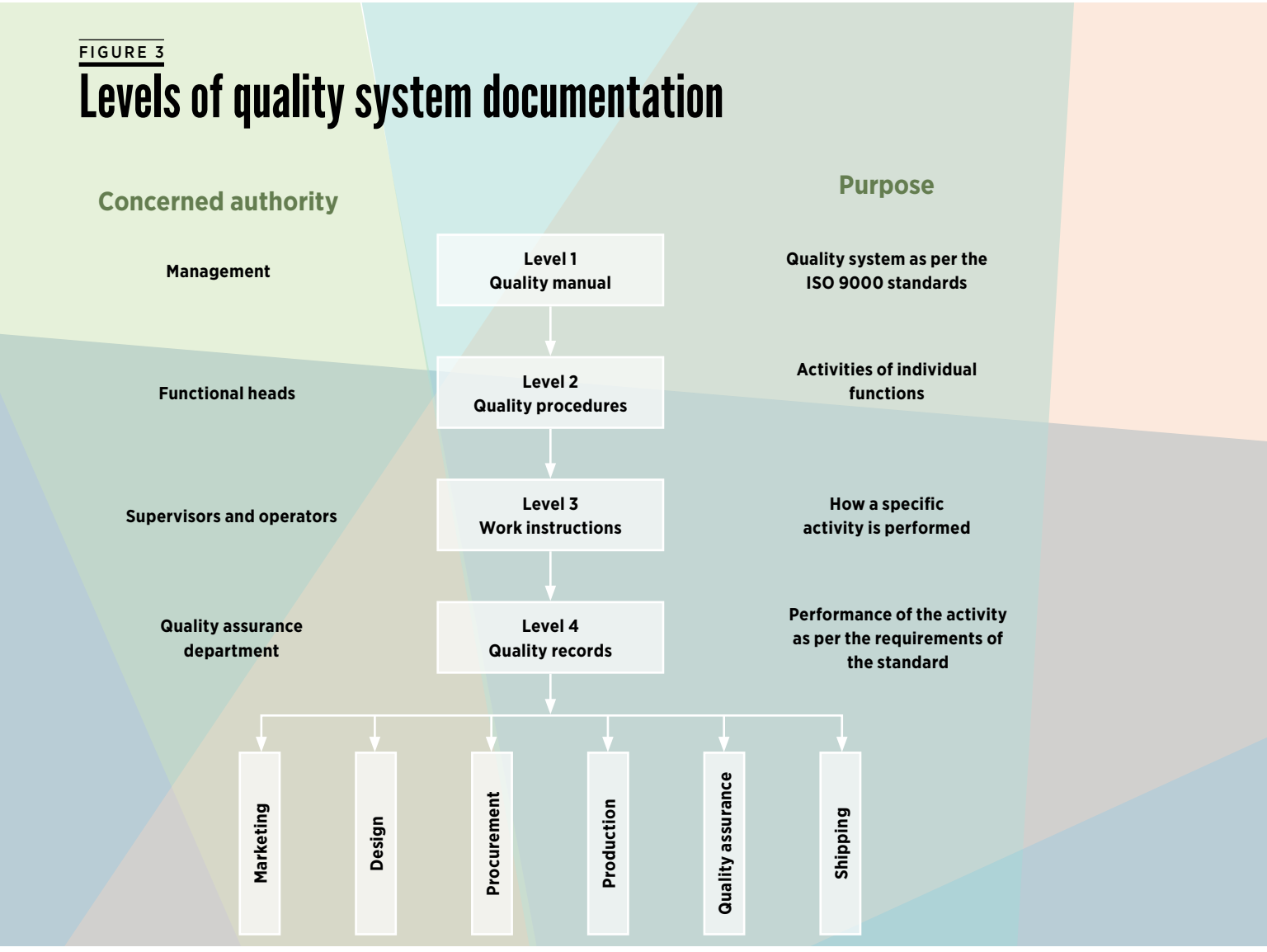
FIGURE 3

Levels of quality system documentation



A vote of confidence

In this journey of quality through standards, always remember what A. Takahashi Matsushita said: "Profits should not be a reflection of corporate greed but a vote of confidence from society that what is offered by the firm is valued." QP

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8. The categories of the various industrial sectors were taken from "The ISO Survey of Certifications 2017," ISO, 2018.

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