3 Quality Standards

Learning objectives

- Explore the concepts of quality standards, implementation and sustainability in the whole quality management system.
- Elucidate pros and minuses of implementing a ISO 9000 in a given organization.
- Deep-dive on ISO 9000 family standards, benefits and requirements for its implementation.
- Explore the steps on how to prepare for an ISO 9000 certification.

Keywords

Standards, auditing, ISO 9000, ASQ, Balbrige.

Required skills

A general knowledge of management on the bachelor's degree level.

Time requirements for the study

You will need approximately 1 hour of your time to study this chapter.

3.1 Introduction

Those are certainly the most important places to see the results of a quality management system. But there can be added value in adopting external standards and receiving certification:

- Getting a quality management system as a package may be cheaper than reinventing the wheel. If you need a fresh start, why not hire experts, get everyone trained, adapt the system to meet your company's needs, and then, as a bonus, get registered or certified, as well?
- Sometimes, registration or certification is a customer requirement. In some cases, our customer might request or require that we, as a vendor, meet the requirements of external standards and be able to prove it. Certification is the more common term for this kind of application for third-party approval, but the ISO uses the term registration. In Quality Management Demystified, we will use the terms interchangeably.
- An expert opinion can show us what we can't see about ourselves. Even when our car is running fine, it makes sense to take it in for a tune-up. Similarly, we may think that everyone is doing a good job, but review by an auditor may show us surprises in time to fix them. External standards can be adopted as internal guidelines, or as a framework for internal guide-lines. When we do this, we can make our own quality management system more effective for ourselves and our customers, and have that validated by an external registrar.

Of course, it only makes sense to adopt a standard if the standard is either required, or it actually improves quality and performance. We'll take a look at ISO 9000 - the most significant worldwide quality standard - and others, so you can see for yourself what standards can do for your company.

3.2 ISO 9000

The ISO, or International Organization for Standardization, is a worldwide body that sets standards for industry. Until the 1980s, most of the standards were technical. For example, the ISO defined the OSI (Open Systems Interconnect) model that is used for both the worldwide telephone network (implemented as Signaling System 7) and the Internet (implemented as TCP/IP). Such standards are beneficial to business because they allow integration and innovation. For example, many companies can build telephone equipment, and they all work together around the world as a result of the SS7 standards. Because SS7 and TCP/IP are both based on the OSI model, they can be integrated with the new technology called VOIP (Voice Over IP), or Internet Telephony.

Although global in scope, the ISO is centered in Europe, and its standardization has been a force supporting the gradual economic and political unification of European countries. In particular, the ISO 9000 series of quality standards makes international commerce with European partners easier.

Variations on the ISO 9000 standard have also been adapted by U.S. auto makers and by the aerospace industry. In each case, the goal is to do with quality management - a business process - what earlier ISO standards did with technical interfaces. The idea is that, if each company complies with the same standard, then it will be much easier for any one company's products to be input in the SIPOC chain for the next company. Rather than specifying specific technical interfaces, ISO requires companies to create their own quality management system (called a quality system or QS). There is a great deal of flexibility in the design of your QS, but it must be focused on meeting customer requirements. The idea is that if the customer side of any interaction has clear requirements, and each company operates to the ISO 9000 standard, industries will be able to design and deliver complex systems - such as cars, elevators, or airplanes - that are safe and of high quality.

To comply with the ISO 9000 standard, a company must set up its own internal Quality System that basically ensures three things:

- A focus on quality defined as customer satisfaction and meeting customer requirements.
- That we, as a company, do what we say and say what we do, and are able to prove it.
- That we use PDCA for correction of problems.

The benefits of actually doing these three things are already clear. A company meets ISO 9000 standards by doing what Taylor demonstrated was the best way of doing business back in 1911. But what is the significance of registration the process of becoming certified as in compliance with ISO 9000 and maintaining that certification?

First of all, your customers may demand it. If you have corporate customers in Europe, this is increasingly likely. But it can happen in the United States as well. There are a number of industry-specific standards similar to ISO 9000 in various stages of development. The aerospace standard is AS 9000. The big three automakers in the United States. created QS 9000, but that is in a state of fluctuation, with another standard, ISO/TS 16949 coming into play. We will simply use the term ISO 9000 generically to refer to all its variations and similar standards. Two other trends are worth noting. One is that some government agencies may require ISO 9000 type certifications of their vendors. The other is that, after major companies require their direct vendors called Tier 1 vendors to be certified, those companies may then require their own vendors called Tier 2 vendors to be certified as well. This is important because it can mean that rather small companies are caught by surprise and suddenly have to rush to get registered or certified, which can be a costly and painful process. It is also relevant for companies changing the market they serve, as ISO 9000 compliance may be an entry requirement for certain markets.

3.3 Why a Standard

This story explains how and why customer quality requirements became industry quality standards in the U.S. auto industry.

The creation of QS 9000 by the big three U.S. automotive companies - GM, Ford, and Chrysler - is something from which we can learn. Each company had found that, in order to meet their own quality and productivity goals, they required vendors to meet quality management requirements as well. That is, they imposed requirements on their supply chain. Initially, each of them had their own proprietary requirements, and also maintained expensive external audit functions that would audit their vendors and suppliers to ensure compliance. All of this was very expensive and each of the big three was footing its own bill.

Inspired and informed by ISO 9000, they got together and adopted ISO 9000 with some automotive-industry specifics and additions, and called it QS 9000 as an independent standard to be audited by a third party. This reduced the costs for the big three. The benefit for the vendors was that they could meet one standard and serve three customers. The cost for vendors was that they had to pay for their own audits to get registered and stay registered.

Note that QS 9000 now governs the vendors' process. Customers still define the product specifications; but since the U.S. auto industry embraced TQM in the 1980s, the car makers saw that they needed to be assured of their vendors' process as well. So that has now moved from being a two-party relationship between vendor and customer to being a three-party relationship maintained through certification to an external standard.

The lesson: Standardization reduces the total cost of quality in an industry by allowing companies to meet one standard and serve multiple customers. However, it may also shift those costs from one party to another.

3.4 The Elements of ISO 9000

ISO 9000 requires only that a company be able to demonstrate that it embraces the principles of quality management and has a quality system (QS) in place to make sure that it is actually doing so. Each company defines its own specific goals and methods. For example, one company might have a practice of eliciting detailed customer requirements for custom work, while another does general market studies to define generic products. One company might choose inspection, another statistical quality control. One company might value innovation, another efficient service.

What is required is that your company define all of these goals in writing, develop written processes for all work related to these goals, and put a quality management system in place that assures that these goals are being met and that work is actually being done as specified. Specifically:

- We create a quality mission statement and a quality manual.
- We define documents that describe how work is to be done. ISO 9000 refers to these as documents; a common term is standard operating procedures (SOP).
- We define a quality system that can produce reports showing that the SOPs were followed in doing the work. Reports would include checklists and records of QC and QA data.
- We train everyone in the parts of ISO 9000 relevant for their work. This is usually a one-day training. Costs can be reduced if workers are trained to write, or at least modify, their own SOPs.
- We set up a QC system that uses PDCA to correct any nonconformities discovered by our quality system.
- We set up a QA system that uses PDCA to ensure that SOPs are correct and up to date, and that ensures that issues discovered about our process move into quality improvement efforts.
- We set up an internal quality auditing system that ensures that all of the above is being used and maintained. We do not need to have fulltime internal quality auditors; we can use staff with other duties part time. But we must have enough internal staff trained in QA that there is someone available to audit any work who was not involved in that work. The primary difference between quality assurance and quality auditing in ISO 9000 is the degree of independence of the auditor.

The ISO 9000 series of standards is divided into sections. ISO 9001 is the most comprehensive. Higher numbers - ISO 9002, 9003, and so forth - are standards focused on particular functions or industries, or more detailed guidance in how to meet these standards. Some of these are options for registration, others are for your information. Recently, ISO has added implementation guidelines in ISO 10000, but these are generally considered together with the ISO 9000 series.

3.5 How to get ISO 9000 Certified

The least expensive and fastest way to prepare for certification is with the help of outside expertise. ISO 9000 consulting and training firms can provide you with complete training for all staff levels, build a plan with you, and pro-vide you with templates for all required documents and reporting systems.

Meeting ISO 9000 requirements is like doing the first year of Deming's five-year approach to transformation through TQM. Key elements are top-down commitment, company-wide training, and employment of PDCA first to bring production under control of inspection or statistical analysis, and then to improve any and all parts of our organization. Like TQM, ISO 9000 only succeeds if it is integrated with organizational management and resolves the conflict between productivity and product quality.

Here are the specific steps to prepare for ISO 9000 registration:

- Evaluate to see if ISO 9000 is right for your company. If it is, make an executive commitment to doing it and engaging the full support of your team.
- Name an executive representative who will communicate with ISO external organizations and lead the internal quality council made up of senior managers and managers.
- Establish one or more quality management implementation teams.
- Perform an internal study to establish a baseline - a report on the current situation of your quality system - and to define the gaps that need to be closed so that your QS meets ISO 9000 requirements. Expert consulting is useful for this, as you do not want merely to meet your own interpretation of ISO 9000 requirements.
- Build an implementation plan that closes all the gaps between your current QS and ISO 9000 requirements.
- Document everything to show evidence of thorough planning and to demonstrate that every process that affects quality has been thought through, planned, and turned into a document or SOP to be followed. The document to be followed can be called a facility quality manual. This is essential for the auditors.
- Maintain your new quality system for three to six months, including auditing it and correcting any nonconformities.

At this point, you are ready to seek formal registration. You contact an ISO 9000 registrar. A registrar is an independent company that, for a fee, audits you to see if you meet - and later to see if you are maintaining - compliance with the ISO 9000 standards. Each registrar is, in turn, registered with an agency - a different one in each country around the world - that ensures all registrars are auditing independently and properly ensuring that they only issue certificates to companies that truly meet the ISO 9000 standard. The process of completing registration looks like this:

- Select a registrar you want to work with.
- Apply for registration.
- The registrar performs a document assessment. In traditional audit language, this is called audit planning. All of your documents are reviewed. The primary question in mind is: Do these documents establish controls that should be in place for all functions that affect quality throughout the organization? If not, you will be asked to remedy these nonconformities before the audit.
- Once controls are demonstrated to exist in the documentation, the registrar sends an audit team to investigate if the controls are actually in place and being used. This includes interviewing personnel to determine that they know and follow correct procedures, and know what to do if a nonconformity is found

in a product, or if a procedure needs to be updated. This is the part of the process where you prove that you do what you say you do.

- If any major nonconformities are found, you remedy them, and the registrar checks them in a brief follow-up audit. In some cases, minor nonconformities can be recognized without delaying certification. You will merely need to demonstrate compliance in time for your first maintenance audit.
- You pay your fee and receive your certificate.
- You maintain your IS system in use and continue your internal audit function. Typically, internal audit should try to check the entire organization once a year, but this is not an ISO requirement.
- Every six months, you arrange for a registrar to perform your external audit so you can maintain registration and keep a valid certificate.

ISO 9000 originally was primarily focused on manufacturing, especially in fields where human safety was a major product concern. This included companies that produced elevators, components for cars and airplanes, and so forth. To some extent, general manufacturing in fields that use less sophisticated engineering has adopted ISO 9000 as well. In addition, use of ISO 9000 can also be applied to service industries. Some say that ISO 9000 still has an engineering/manufacturing flavor. Companies in software development might prefer CMMI to ISO 9000, as it is industry specific. Also, in choosing a consulting firm or registrar, it makes sense to pick someone who understands your industry and someone who you believe will work well with you.

This last point raises an interesting issue. Is ISO 9000 implemented by different registrars with essentially the same rigor? Or does a company get off more lightly by choosing a more lenient registrar? I was discussing ISO 9000 and CMMI with the head of quality for a major research firm, and he said simply, “There is a lot of shopping around for registrars.” But the question is, who is really better off? Is it the company that chooses a more lenient registrar and has to do less work to come into compliance, or the company that chooses a more demanding registrar, and is pushed to achieve higher quality?

3.6 Pluses and Minuses of ISO 9000

As a quality management methodology, how does ISO 9000 stack up against TQM and other methods? It is rudimentary. To put it another way, it is a first step, but it is the right first step. A company that truly wants to transform through quality management would do well to begin with ISO 9000. I mean this in two senses. First, adopting ISO 9000 will be the equivalent of the first year of a TQM initiative. Second, adopting ISO 9000 requires a company to establish clear quality requirements and procedures, which is an essential step in preparation for the application of statistics to quality problems.

In one way, ISO 9000 does move in a direction that is different from TQM. The emphasis on auditing - both internal and external - is greater. On one level, this simply reflects the fact that, in going for ISO 9000 registration, a company is setting out to prove that it has an effective quality system in place, rather than just allowing its products and customer service to demonstrate that to customers in the marketplace. On another level, it could reflect a deeper issue of corporate culture. In TQM, the way a culture of quality spreads through a company is through the influence and guidance of leadership. This is supported by high levels of training and by recruitment and indoctrination practices that select

people who fit in well with corporate culture and values. As long as people who are committed to the company and to quality are selected, they can be included in the TQM company somewhere, and can move to a job that is a good fit if necessary. This fits very well with Theory Y management.

ISO 9000 is possibly more compatible with Theory X management. It relies more on independent validation proving that good work is being done, and less on influencing each worker to evoke a commitment to quality. It puts more resources into independent checking, and less into training. ISO 9000 can certainly be adapted to a TQM company at reasonable cost, because any TQM quality engineer can easily qualify to be an ISO 9000 quality auditor, and then offer services to other departments. But, if a company is in a situation where, due to culture or other factors, it cannot influence its entire company to accept TQM, then ISO 9000 might actually be preferable. For example, if a company uses consultants or brings in new employees for short-term project work, then ensuring quality through the ISO 9000 audit approach might be more effective than providing a lot of TQM training to people who will only be with the company for a relatively short time. Or if a company is organized as a loose cluster of acquired companies, it might be easier for the highest executive level to require ISO 9000 and support other initiatives, but allow the relatively independent operating groups leeway in choosing when and how to move quality beyond ISO 9000 to a total approach.

3.7 Other Awards, Standards and Associations

The Balbridge National Quality Program

The Baldridge Award was established by the U.S. federal government in 1987, during the heyday of the American TQM era. It is administered by the National Institute of Standards and Technology (NIST), a division of the United States Chamber of Commerce, supported by the American Society for Quality (ASQ). It was named after the U.S. Secretary of Commerce from 1981 to 1987, Malcom Baldridge. Winning a Baldridge Award was considered a demonstration of the highest achievement in TQM, and many companies sought the distinction. Designed to be similar to Japan's Deming award, it has evolved over the years. Originally focused on manufacturing, it now focuses on the organizational capability for quality and specifically gives awards in five areas: manufacturing, service, small business, education, and healthcare. Two interesting aspects of the award are that it applies to not-for-profit as well as for-profit organizations, and that organizations traditionally not considered to be part of business - such as school districts - can win the award.

The American Society for Quality (ASQ)

The American Society for Quality (ASQ) is a leading organization in the field of quality management. Its web site, www.asq.org opens with an excellent quality management primer, and the organization, as a whole, provides a tremendous amount of support for any company or organization seeking to improve its quality management using any methodology.

The Project Management Institute (PMI)

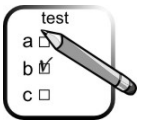
The Project Management Institute (PMI), at www.pmi.org is a global professional association for the advancement of project management. Project management and quality management are closely allied fields. Both focus on meeting customer requirements. Project success requires good quality management. At the same time, any change to an organization - such as a quality improvement program - is best organized as a project or a set of projects. The PMI is also advancing standards at a more strategic level, including the Organizational Project Management Maturity Model (OPM3), which integrates the CMM concept of maturity with the capability to do good project management; program management, which focuses on large activities consisting of many projects and other related work; and portfolio management, which evaluates programs as an investment of limited resources. The PMI - both at the global level and also through its local chapters - is an excellent resource that supports companies in developing a results-oriented structure for delivering either internal change or new products and services to customers.

Summary

Just as a focus on quality should support - rather than be a sideline to - meeting core business goals of customer satisfaction and profit, so certification, or registration, or applying for an award, or developing a connection with a professional association should support improved quality and business success, and not be pursued for its own sake. That is, any of these activities should be aligned with corporate goals and evaluated for its value to the bottom line.

That said, many companies will find value in using one or more of these resources. It is simply less expensive to buy - or even pick up for free - the wheel of continuous quality improvement than it is to reinvent the wheel yourself. I do not mean that a quality management system can be purchased off the shelf and installed. That simply won't work. A deep willingness to change one's own philosophy and character, and to lead others to do the same, is essential to quality management success. But guidance and support for that process can be found in standards, awards, and professional associations.

Review questions



1. Which of these is not true about ISO 9000?

(a) ISO 9000 is the European quality standard.

(b) ISO 9000 guidelines match the initial focus of a TQM initiative.

(c) ISO 9000 focuses on quality audits and quality assurance more than on quality control.

(d) ISO 9000 standards and their variants are used in various industries worldwide. Describe the concepts of sample and population highlighting their differences.

2. Which of these is *not* true of an ISO 9000 internal auditor?

(a) The auditor reviews procedures to ensure that documents (SOPs) are being followed and that records confirm this.

(b) The auditor must be trained in ISO 9000 auditing.

(c) Although the auditor may do other work in the company, he must confirm his independence in relation to each area he audits.

(d) To maintain independence, the auditor must work only as a full-time auditor.

3. ISO 9000 requires

(a) inspection to ensure customer satisfaction.

(b) use of statistical quality control.

(c) either inspection or statistical quality control, whichever is appro-priate to your business.

(d) an annual internal audit program reviewing all ISO 9000 requirements.

4. Which of the following is not a criterion of the Malcolm Baldridge Award?

(a) Leadership

(b) Strategic planning

(c) Quality management

(d) Customer and market focus

5. Which of these standards, prizes, awards, or associations would not be applicable to any North American company seeking to improve quality?

(a) The Deming prize

(b) ISO 9000

(c) The Baldridge Award

(d) IEEE

References

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