

5.1 QUALITY MANAGEMENT SYSTEM

I. INTRODUCTION

Total Quality Management (TQM) is a management approach that involves the entire organization in improving products and services to meet or exceed customer expectations. A Quality Management System (QMS) is a set of rules that helps organizations meet customer needs and statutory and regulatory requirements. ISO 9001:2015 is a globally recognized QMS standard that can help organizations improve their performance.

Here are some principles of TQM:

Customer focus: Put the customer first and meet or exceed their expectations

Employee commitment: Involve all employees in quality improvement

Continuous improvement: Commit to ongoing improvement of products and processes

Process orientation: Emphasize the importance of well-defined and controlled processes

Fact-based decision making: Make decisions based on facts

Deliver high-quality work: Deliver high-quality work the first time

Strategic project approach: Approach projects strategically

Foster cooperation and mutual respect: Foster a culture of cooperation and mutual respect

Some benefits of a QMS include: Meeting statutory and regulatory requirements, cutting costs and reducing waste, improving customer and employee satisfaction, and continually improving organizational processes.

II. Benefits of ISO Registration:

ISO registration, or certification, can provide many benefits for an organization, including:

Quality: ISO certification demonstrates a commitment to quality and can improve the quality of products and services.

Customer satisfaction: ISO certification can improve customer satisfaction by ensuring that the organization meets customer requirements and provides a consistent, reliable service.

Efficiency: ISO certification can improve operational efficiency by standardizing processes and reducing waste.

Employee morale: ISO certification can improve employee morale by defining roles and responsibilities, establishing training procedures, and making employees accountable.

Credibility: ISO certification can increase credibility and recognition, which can help an organization compete in the market.

Regulatory compliance: ISO certification can help an organization align with industry regulations and standards.

Risk management: ISO certification can help an organization improve its risk management by emphasizing risk-based thinking.

Supplier relationships: ISO certification can help an organization improve relationships with suppliers and partners. ISO stands for International Organization for Standardization, and it's an independent, non-governmental organization

III. Key benefits of a quality management system

1. Identify risks and opportunities
2. Prevent problems from reoccurring
3. Boost your marketing and sales efforts
4. Improve employee performance
5. Improve your control over the business

Identify risks and opportunities:

The best way to deal with quality issues is to prevent them from occurring in the first place. To achieve this goal, ISO 9001—the popular quality management standard—asks you to identify potential risks to your business and control them in a structured way. This risk-based thinking leads to fewer surprises, improved planning, more effective decision-making and better relationships with suppliers, customers and employees.

“We sit down and think about the things that have gone wrong historically,” Mohamud says. “And we try to prevent those things from happening. It allows you to reduce the likelihood of things going wrong in the first place.” At the same time, ISO asks you to look for opportunities for your business and consider how to take advantage of them in an organized fashion.

Prevent problems from reoccurring

Too often businesses repeat the same mistakes because they don't have a system to record and correct problems as they occur. ISO requires you to maintain careful records of problems, seek out their root causes and come up with lasting solutions. The result is less waste, better quality and lower costs.

“There's so much waste that comes from rework and defective products and services that could be prevented,” Mohamud says. “With ISO, you figure out what the problem is and correct it. You also make it part the organization's knowledge so you prevent it from reoccurring.”

Boost your marketing and sales efforts

Just think of how many times you've seen companies promote their ISO certification in advertising, on their website and even on a banner outside their building. As an internationally recognized quality management system, achieving ISO certification will support your marketing and help increase your sales. Indeed, many large companies require their suppliers to be ISO certified. And certification can be particularly important if you want to enter foreign markets. "We see a lot of SMEs that want to grow and sell outside of Canada, and they're almost always asked to have ISO 9001 and any industry specific ISO standard," Mohamud says.

Improve employee performance

Employee morale improves when they know you are committed to eliminating waste and producing the highest quality products and services. ISO also requires you define tasks (who does what), eliminate skills gaps in your business and communicate your quality policies to employees. "When things are not done in an organized fashion, we see a lot of confusion and doubt for the employees," Mohamud says. "With ISO, you're giving people the comfort of a framework in which they can succeed. You're giving them the tools, the resources, the training to do their jobs well. When it's organized people are going to be happier and they're going to want to do better."

Improve your control over the business

ISO requires you monitor, measure, analyze and evaluate the effectiveness of your quality management system. By doing so, you will generate performance metrics that allow you to judge how well you're doing and where you need to improve. These are powerful tools for gaining insight into your business and make better decisions.

"As an entrepreneur, it helps you to get the full picture and then say: Maybe, we need to drill down in more detail to find out where we need to focus our improvement efforts. Besides creating a stronger, more efficient and productive company today, ISO can also make your business more attractive to buyers when it comes time for you to sell, Mohamud says. "You are demonstrating your commitment to an effective management approach with quality at its heart to your suppliers, your customers, your shareholders and potentially a company that wants to buy you."

IV. ISO 9000 Series of Standards:

The ISO 9000 family of quality management systems (QMS) is a set of standards that helps organizations ensure they meet customers and other stakeholder needs within statutory and regulatory requirements related to a product or service. ISO 9000

deals with the fundamentals of quality management systems, including the seven quality management principles that underlie the family of standards. ISO 9001 deals with the requirements that organizations wishing to meet the standard must fulfil.

Third-party certification bodies provide independent confirmation that organizations meet the requirements of ISO 9001. Over one million organizations worldwide are independently certified, making ISO 9001 one of the most widely used management tools in the world today. However, the ISO certification process has been criticized [self-published source?] as being wasteful and not being useful for all organizations.

ISO 9000 is defined as a set of international standards on quality management and quality assurance developed to help companies effectively document the quality system elements needed to maintain an efficient quality system. They are not specific to any one industry and can be applied to organizations of any size. ISO 9000 can help a company satisfy its customers, meet regulatory requirements, and achieve continual improvement. It should be considered to be a first step or the base level of a quality system.

ISO 9000:2000:

ISO 9000:2000 refers to the ISO 9000 update released in the year 2000.

The ISO 9000:2000 revision had five goals:

Meet stakeholder needs

Be usable by all sizes of organizations

Be usable by all sectors

Be simple and clearly understood

Connect quality management system to business processes

ISO 9000:2000 was again updated in 2008 and 2015. ISO 9000:2015 is the most current version.

ISO 9000:2015 principles of Quality Management

The ISO 9000:2015 and ISO 9001:2015 standards are based on seven quality management principles that senior management can apply to promote organizational improvement.

Customer focus

Understand the needs of existing and future customers
Align organizational objectives with customer needs and expectations
Meet customer requirements
Measure customer satisfaction
Manage customer relationships
Aim to exceed customer expectations



2. Leadership

Establish a vision and direction for the organization
Set challenging goals
Model organizational values
Establish trust
Equip and empower employees
Recognize employee contributions
Learn more about leadership

3. Engagement of people

Ensure that people's abilities are used and valued
Make people accountable
Enable participation in continual improvement
Evaluate individual performance
Enable learning and knowledge sharing
Enable open discussion of problems and constraints
Learn more about employee involvement

4. Process approach

Manage activities as processes
Measure the capability of activities
Identify linkages between activities
Prioritize improvement opportunities
Deploy resources effectively
Learn more about a process view of work and see process analysis tools

5.Improvement

Improve organizational performance and capabilities
Align improvement activities
Empower people to make improvements
Measure improvement consistently
Celebrate improvements
Learn more about approaches to continual improvement
Evidence-based decision making
Ensure the accessibility of accurate and reliable data
Use appropriate methods to analyze data
Make decisions based on analysis
Balance data analysis with practical experience
See tools for decision making

6. Relationship management

Identify and select suppliers to manage costs, optimize resources, and create value
Establish relationships considering both the short and long term
Share expertise, resources, information, and plans with partners
Collaborate on improvement and development activities
Recognize supplier successes
Learn more about supplier quality and see resources related to managing the supply chain.

V. NEED FOR ISO 9000- ISO 9000-2000 QUALITY SYSTEM

Basic Requirements of ISO 9001

Procedure to cover all processes in the business

Monitoring process to ensure effectiveness
Keeping adequate record
Defect verification and appropriate correction
Regular review of individual processes
Facilitating continual improvement

Benefits of ISO Registration

Increase in internal quality – reduction of scrap, rework etc
Production reliability – measure of breakdowns, time and shift management etc
External quality – acceptance by customers, less claims, return of goods
Time performance – marketing, delivery, production time etc
Cost of poor quality – scraps and rework

ISO 9000 Family

ISO 9000:2000 QMS – Fundamental and Vocabulary

Basic QMS

Guidance document for certification

Revised in ISO 9000:2005

ISO 9001:2000 QMS – Requirements

Design, development and installation

Customer satisfaction through products and service

ISO 9004:2000 QMS – Guidelines for Performance

Continuous improvement

Enhance the mature system

VI. PROCESS OF OBTAINING ISO CERTIFICATION

What Are the Steps of the ISO Registration Process? **ISO Registration Process:**

The ISO Registration Process comes after your company's ISO 9001 audit. The purpose of registering your company is to show that you've met the requirements. And to do this effectively, you will need to follow eight essential steps.

Finding an ISO 9001 Registrar

You'll need to begin searching for an ISO registrar during the 2 to 3 months your company is still building its quality system. You can search the ANSI-ASQ National Accreditation Board (ANAB) to select the registrar right for you.

Registrars must meet the requirements of the ISO Accreditation Bodies. These requirements include things such as independence; Registrars cannot consult for instance. This system ensures uniformity in the registration process.

Accreditation Bodies maintain directories of the Registrar organizations that they accredit. These directories are available on their websites. You can normally find these websites by doing a search on the Accreditation Body's name or initials.

A directory of registrars in the U.S. can also be found at the ANSI-ASQ National Accreditation Board website which offers access to a searchable database of accredited registrars in the United States.

In Canada, contact the Standards Council of Canada for a list of registrars. All other countries should consult the accreditation authority or member body for their country. Consult the ISO website for a complete list of ISO Member bodies.

Selecting an ISO Registrar

Select a registrar that has experience within the scope category of your specific industry, which you can also find on the ANAB site. Keep in mind accreditation, scheduling issues, fees and comfort level when selecting the registrar right for you.

Registrar qualifications are a key consideration. As you research Registrars you will notice that some appear to be very limited in scope just based on their names. Registrars must be accredited in a particular industrial sector in order for them to be able to certify a company in that sector. Some Registrars are accredited in several if not all sectors; others specialize in certain sectors. The best approach to evaluating a Registrar's qualifications for your industrial sector is to contact the Registrar.

After qualifications, price is always a concern. Be sure to evaluate the total cost including expenses, fees and the cost of surveillance.

Probably as important as price, within limits of course, is the overall experience a client gets with a registrar. Important areas to consider are the interpersonal skills of the auditors; the office support and ability to get questions answered; are the audits a value-added experience, will the Registrar work with you, how flexible are they in adjusting dates – how many weeks notice.

Creating an ISO Application

A company and a registrar will agree on the application contract. This is an important step of the ISO Registration Process because it defines the rights and obligations of both parties, and includes liability issues, confidentiality and access rights.

Conducting a Quality Document Review

The registrar will require a copy of your quality manual and procedures to verify that all the requirements of the standard are addressed. The ISO Registration Process is not a quick process, be sure to allow 2-4 weeks in advance for the registrar to fully review all of the necessary documents.

Determining Pre-assessment Need

Though optional, this 2-4 week initial review of the system identifies any significant omissions or weaknesses. It saves time and allows the registrar to assess any issues and resolve logistics before the actual assessment audit.

The Pre-assessment is an initial review of your Quality Management System to identify any significant omissions or weaknesses in the system and provide your organization an opportunity to correct any deficiencies before the regular registration assessment is conducted.

Issuing an ISO Assessment

During the audit, or physical onsite inspection of procedures in action, the auditors will issue findings if they assess anything that doesn't meet requirements, or nonconformities. The length of this step of the ISO Registration Process will depend on the scope of the audit and the size your organization.

Completing ISO 9001 Registration

After all of the findings are put into the ISO audit report and nonconformities are addressed, your company has the option to register as ISO 9001 conformant. You will receive a certificate and can also be listed in a register, which the company can use to publicize its registration and use in advertising.

Checking with Surveillance Audits

To ensure that the system is maintained and that changes don't result in deficiencies in the system, registrars perform regular surveillances of the system. Over the three-year period of your certificate, auditors will perform one full and two partial checks

of your system.

VII. ESSENTIAL STEPS TO ISO CERTIFICATION

The costs for developing and registering a formal management system vary depending on the size and complexity of your organization and your internal processes.

First—There are developmental costs, namely the time spent documenting and implementing the system.

Second—There are costs associated with training employees to prepare the necessary documents and to plan and conduct effective internal audits.

Third—There is the cost of registration, which includes conducting the audit and registering the management system. The cost depends on the number of locations, the scope of work, the number of shifts and so on.

1. Develop your management system

Identify your core or business processes. Document processes with the involvement of employees.

Review, approve and distribute the documents to those who need access to the information.

2. Implement your system

Ensure procedures are being performed as they are described in your documentation. Ensure employees are trained properly for the tasks they are performing. Create effective reporting systems to cover inspection, testing, corrective actions, preventive actions, management, review, meetings, objectives, statistical techniques and so on. Monitor the effectiveness of your processes through the use of measurable data, where possible. Review and take action to improve in the areas required.

3. Verify that your system is effective

Conduct the audit and review the processes and system for compliance and effectiveness. Observe, interview people and look at sample records. Identify and report strengths and weaknesses of the management system. Take corrective or preventive action as required.

4. Register your system

Select the appropriate auditing body for external registration. Submit your

management system documentation for review to ensure it complies with the applicable standard. Prepare for review by an external auditor to confirm that the system's requirements are being satisfied and that the management system is implemented effectively.

VIII. ADVANTAGES OF ISO CERTIFICATION

Benefits of ISO 9001:2008/ISO 9001:2015 to your business

ISO 9001 aims to provide a practical and workable Quality Management System for improving and monitoring all areas of your business. Achieving the ISO 9001 standard is not about establishing a set of procedures that are complicated and difficult to manage. The aim is to provide a workable management system that is suitable for your organization. With the right support and the knowledge of your employees, you will end up with a system that will improve all areas of your organization.

Implementing an effective and robust ISO 9001 Quality Management System (QMS) will help you to focus on the important areas of your business and improve efficiency. The management processes that are established throughout your business will provide a sound foundation, leading to increased productivity and profit. This in turn will improve your customer acquisition and retention.

Some of the main benefits of ISO 9001 certification include:

Suitable for both small and large organisations

Better internal management

Less wastage

Increase in efficiency, productivity and profit

Improved customer retention and acquisition

Consistent outcomes, measured and monitored

Globally recognised standard

Compatible with other ISO standards

Benefits of ISO 9001 to your customers

The ISO 9001:2008/ISO 9001:2015 standard is recognised worldwide and your customers will understand the benefits of working with companies that are ISO 9001 certified. In fact, some of your customers will only do business with certified

companies because it gives them assurance that your management systems are constantly assessed and approved.

They will know from experience that working with ISO 9001:2008/ISO 9001:2015 certified companies provides many advantages:

Minimizes mistakes

Improves reporting and communications

Better quality products and service

More reliable production scheduling and delivery

Standards maintained by annual assessments

IX. NEW VERSION OF ISO STANDARDS

The International Organization for Standardization (ISO) is a worldwide federation of national standards' bodies from more than 140 countries (one from each country). ISO standards are documented quality systems and activities, used as the basis for adoption of uniform quality systems norms for international exchange of goods and services.

In fact, 'ISO' is a word, derived from the Greek word *ISO* meaning 'equal', which is the root of the prefix 'ISO' that occurs in a host of terms, such as 'isometric' (of equal measure or dimensions) and 'isonomy' (equality of laws, or of people before the law). From 'equal' to 'standard', the line of thinking that led to the choice of 'ISO' as the name of the organization is easy to follow.

The name 'ISO' is used around the world to denote the organization, thus avoiding a plethora of acronyms resulting from the translation of 'International Organization for Standardization' into the different national languages of members, such as, IOS in English, OIN in French, etc.

The objectives of ISO 9001:2000 quality management systems for an organization are:
To identify the goals that the organization intends to achieve. Goals may be efficiency and profitability, consistently meeting customer requirements, etc.

To consistently meet customer requirements

To achieve customer satisfaction

To enhance market share

To sustain market share

To improve communications and morale in the organization

To reduce costs and liabilities

To increase confidence in the production system

The organization meeting expectations of various stakeholders, such as, customers, suppliers, shareholders, employees, and the society achieve all these objectives.

Contents of ISO 9001:2015

A fish wholesaler in Tsukiji, Japan, advertising its ISO 9001 certification ISO 9001:2015 Quality management systems — Requirements is a document of approximately 30 pages available from the national standards organization in each country. Only ISO 9001 is directly audited against for third-party assessment purposes.

Contents of ISO 9001:2015 are as follows:

Section 1: Scope

Section 2: Normative references Section 3: Terms and definitions Section 4: Context of the organization Section 5: Leadership

Section 6: Planning

Section 7: Support

Section 8: Operation

Section 9: Performance evaluation Section 10: Continual Improvement

Essentially, the layout of the standard is similar to the previous ISO 9001:2008 standard in that it follows the Plan, Do, Check, Act cycle in a process-based approach but is now further encouraging this to have risk-based thinking (section 0.3.3 of the introduction).

The purpose of the quality objectives is to determine the conformity of the requirements (customers and organizations), facilitate effective deployment and improve the quality management system.

Criticisms of ISO 9001 certification

A common criticism of ISO 9000 and 9001 is the amount of money, time, and paperwork required for a complete implementation of the ISO 9001 certification. Dalglish cites the "inordinate and often unnecessary paperwork burden" of ISO, and says that "quality managers feel that ISO's overhead and paperwork are excessive and extremely inefficient". The level of minimum documentation for a minimum scope organization has been greatly reduced, going from ISO 9001:2000 to ISO 9001:2008

to ISO 9001:2015.

According to Barnes, "Opponents claim that it is only for documentation. Proponents believe that if a company has documented its quality systems, then most of the paperwork has already been completed". Wilson suggests that ISO standards "elevate inspection of the correct procedures over broader aspects of quality", and therefore, "the workplace becomes oppressive and quality is not improved".

One study showing reasons for not adopting this standard include the risks and uncertainty of not knowing if there are direct relationships to improved quality, and what kind and how many resources will be needed. Additional risks include how much certification will cost, increased bureaucratic processes and risk of poor company image if the certification process fails. According to John Seddon, ISO 9001 promotes specification, control, and procedures rather than understanding and improvement. Wade argues that ISO 9000 is effective as a guideline, but that promoting it as a standard "helps to mislead companies into thinking that certification means better quality, ... [undermining] the need for an organization to set its own quality standards". In short, Wade argues that reliance on the specifications of ISO 9001 does not guarantee a successful quality system.

The standard is seen as especially prone to failure when a company is interested in certification before quality. Certifications are in fact often based on customer contractual requirements rather than a desire to actually improve quality. "If you just want the certificate on the wall, chances are you will create a paper system that doesn't have much to do with the way you actually run your business", said ISO's Roger Frost.

X. Specific Standards - AS 9100, TS16949 and TL 9000

AS 9100, TS 16949, and TL 9000 are quality management systems (QMS) that specialize in specific industries:

AS 9100

For the aerospace industry, this standard was released in 1999 by the European Association of Aerospace Industries and the Society of Automotive Engineers. It combines the requirements of the FAA, DOD, and NASA, while also meeting the needs of the industry.

TS 16949

For automotive suppliers, this standard combines the quality requirements of US suppliers with those of German, French, and Italian automakers. It aims to reduce variation and waste, prevent defects, and provide continuous improvement.

TL 9000

For the telecommunications industry, this standard specializes the generic ISO 9001 standard to meet the needs of the ICT sector. It focuses on customer-organization relationships, continual improvement, and effective performance-based measurements.

