ISO 9001 Certification for Small Businesses

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INSTILLING *TRUST*

Small businesses come and go in the United States all the time, but a business' success often depends on **customer trust**. The ISO 9001:2015 Standard for Quality helps companies create, implement, and maintain a finely tuned **Quality Management System** (QMS) that encourages small businesses to thrive and creates a culture of producing consistent products and services customers can rely on.

Small businesses set goals through the Standard for **constantly improving customer experiences and satisfaction**. This guide walks you through the clauses of the standard and takes the technical language of the ISO standard and provides easy-to-understand applications for your business.

Feel free to reach out to me if I can answer any of your questions after you review the guide.

Stephanie Kline, CEO

THE ISO 9001:2015 STANDARD

What is ISO 9001?

ISO 9001 is a quality management system standard focused on best practices for the production and delivery of a company's products/services. It focuses on company efficiency, customer satisfaction, and continuous improvement. The standard walks companies through the development and implementation of a quality management system (QMS).

Who Uses it?

Any size and type of organization, even virtual companies, can certify to ISO 9001. Currently there are more than a million organizations certified to the standard world-wide.

Who Wrote it?

The International Organization for Standardization (ISO) wrote the standard. The most recent update was in 2015 (hence the name ISO 9001:2015). It was confirmed as recently as 2021 by ISO as well.

Who Issues the Certificate?

ISO 9001 certificates are issued by a third-party Registrar (such as CertFast, Inc.) after successful completion of the certification audit. The auditors review the company's policies, processes, and documentation to ensure that the organization is in compliance with the Standard. Certification is good for 3 years if annual surveillance audits are conducted. At the end of every 3-year cycle, a re-certification audit occurs to maintain certification.

What Requirements are Included?

ISO 9001:2015 requirements are organized as follows:

- Context of the Organization
- Leadership
- Planning
- Support
- Operation
- Performance Evaluation
- Improvement

The Quality Management System (QMS) is composed of these requirements. The system should be described in company documentation and can include things like a quality manual, any necessary procedures, work instructions, records, and other information used for the company to operate. A well implemented system will help the company consistently deliver quality products/services in a timely manner and meet customer requirements at a high level of satisfaction.

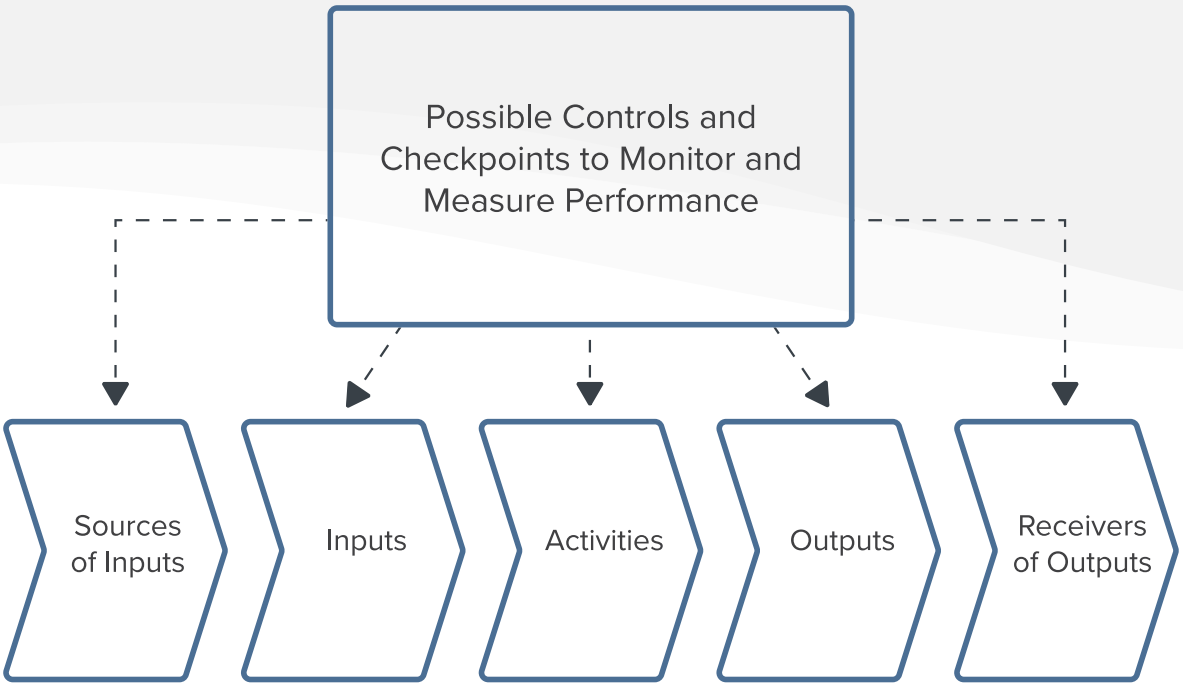
THE ISO 9001:2015 STANDARD FOLLOWS THE PROCESS APPROACH

The process approach follows the PDCA Cycle (Plan, Do, Check, Act). It includes the implementation of processes and improvements, so the outcome results in consistently satisfied customers.

The ISO 9001 Standard states "...the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results." (0.3.1)

During the ISO 9001 certification process you will evaluate and monitor six possible controls and check points:

- Source of Inputs - the processes and policies those who impact inputs (customer requirements as an example)
- Inputs - the physical materials, information, or resources secured to make products/services
- Activities - actions in the making/delivering of product/services
- Outputs - the quality of the final deliverable
- Receivers of Outputs - the processes of the customers that use the final product or service



This diagram of a process takes what the customer wants as your product/service and looks at the things your company does to produce the end product/service.

THE PROCESS *APPROACH*

RISK-BASED *THINKING*

(Found Throughout the Standard)

An important part of the updated ISO 9001:2015 standard is called Risk-Based Thinking. It involves considering potential risks and benefits/rewards of evaluating risks. It is a proactive approach, more like a "game-day quarterback" instead of a "Monday-morning quarterback" style of management.

What does the Standard Say about Risk-Based Thinking?

"To conform to the requirements of this International Standard, an organization needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results, and preventing negative effects." (0.3.3)

ISO 9001 Requirements:

0.3.3 Risk-Based Thinking

6.1 Actions to Address Risks and Opportunities

8.1.1 Operational Risk Management

CONTEXT OF THE *ORGANIZATION*

(Found in Clause 4)

Context of the Organization is somewhat of an abstract concept, but it basically asks your company to address the external and internal factors impacting your business. It shows you how the QMS should be developed so it meets business goals and customer expectations. An example of external factors could be the price of a raw material. An example of an internal factor could be a senior executive retiring and needing to be replaced.

What does the Standard say about Context of the Organization?

"The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

"The organization shall monitor and review information about these external and internal issues. (4.1)

ISO 9001 Requirements:

4 Context of the organization

4.1 Understanding the organization and its context

4.2 Understanding the needs and expectations of interested parties

4.3 Determining the scope of the quality management system

LEADERSHIP

(Found in Clauses 5, 6, 7)

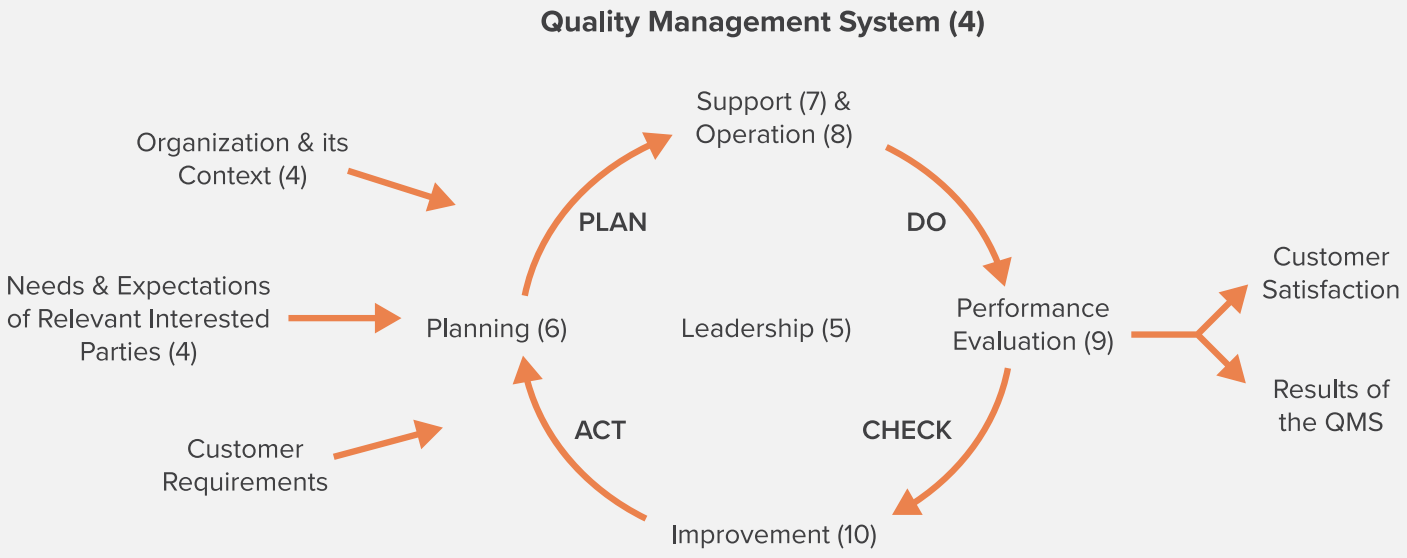
One of the new additions in ISO 9001:2015 is the involvement of Leadership in the Standard. Gone are the days when the Quality Manager does everything to maintain a QMS. For a QMS to be beneficial to a company, Leadership needs to be involved and committed to quality and customer satisfaction. Let's investigate this a bit more. There are required "leadership meetings" where minutes are taken. These meetings, sometimes called Management Reviews, can be incorporated into your regular business meetings, but the intent is to address key goals, their progress, and any concerns or risks in meeting strategic business goals and the overall company objectives of quality products/services. The meetings should also address if management needs to provide any resources for the QMS.

What does the Standard Say about Leadership?

"Top management shall demonstrate leadership and commitment with respect to the quality management system... Top management shall demonstrate leadership and commitment with respect to customer focus..." (5.1.1, 5.1.2)

ISO 9001 Requirements:

5 Leadership
5.1 Leadership and commitment
5.1.1 Leadership and Commitment for the Quality Management System
5.2 Policy
5.2.1 Establishing the quality policy
5.2.2 Communicating the quality policy
5.3 Organizational roles, responsibilities, and authorities
6.2 Quality objectives and planning to achieve them
7.1 Resources



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PLANNING

(Found Throughout the Standard)

Yes, that's right, you heard correctly. No more "flying by the seat of your pants." To have an ISO 9001:2015 certified QMS your company needs to do some planning. Planning needs to include measurable goals/quality objectives. If your company is going to add a new product line or service, the QMS asks Leadership to evaluate the risks and opportunities associated with it and work toward continuous improvement of your systems and customer satisfaction levels.

What does the Standard say about Planning?

"When planning for the quality management system, the organization shall consider the issues referred to in 4.1 (context) and the requirements referred to in 4.2 (expectations of interested parties) and determine the risks and opportunities that need to be addressed... The organization shall establish quality objectives at relevant functions, levels, and processes needed for the quality management system." (6.1.1, 6.2.1)

ISO 9001 Requirements:

6.0 Planning
6.3 Planning of changes

SUPPORT + *RESOURCES*

(Found in Clause 7)

Simply put, management is responsible to provide competent people and resources (materials/ equipment/ money) to provide the opportunity for a successfully implemented QMS. Management should provide a work environment with good training and documentation for making and providing quality goods and services.

What does the Standard say about Support and Resources?

"The organization shall determine and provide the resources needed for the establishment, implementation, maintenance, and continual improvement of the quality management system." (7.1.1)

ISO 9001 Requirements:

7 Support
7.1.1 General
7.1.2 People
7.1.3 Infrastructure
7.1.4 Environment for the operation of processes
7.1.5 Monitoring and measuring resources
7.1.6 Organizational knowledge
7.2 Competence
7.3 Awareness
7.4 Communication
7.5 Documented information
7.5.1 General
7.5.2 Creating and updating documented information
7.5.3 Control of documented information

CUSTOMER FOCUS + *SATISFACTION*

(Clauses 5, 9)

Believe it or not, these two things are very different. Having a "customer focused" QMS, means everything that is done in the company is done with the customers' needs in mind, meeting customer expectations, and meeting customer requirements. Customer satisfaction is the outcome of being customer focused. If you do the first part correctly, the second part should yield great results and hopefully produce high Net Promoter Scores and higher customer satisfaction levels.

What does the Standard say about Customer Satisfaction?

"The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring, and reviewing this information." (9.1.2)

ISO 9001 Requirements:

5.1.2 Customer Focus

9.1.2 Customer Satisfaction

OPERATIONS *CONTROL*

(Found in Clause 8)

Operations is about what activities your company does to create products and provide services to your customers. It includes the whole process from sales, to making the product/delivering the service, to follow-up service (if applicable). The requirement asks the organization to address the "control of nonconforming outputs." Examples of nonconforming outputs would be a product that is "out of specification," or doesn't meet the customer requirements, or a service that was provided with a poor satisfaction rating or review.

What does the Standards say about Operations Control?

"The organization shall plan, implement, and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6... The output of this planning shall be suitable for the organization's operations.

"The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

"The organization shall ensure that outsourced processes are controlled (see 8.4)." (8.1)

ISO 9001 Requirements:

8 Operation

8.1 Operational planning and control

KEY BUSINESS *PROCESSES*

(Found in Clause 8)

Key business processes are activities that a company does to provide its products/services. Each process in your company needs to be documented, controlled, and improved. They are specific to your company. If your company is involved in the design of products and services, these would be included in your scope of certification. Make sure to talk to CertFast about how to correctly define your scope of certification and whether it should include design, because this part can be especially tricky.

What does the Standard say about Key Business Processes?

"The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined" (8.1)

ISO 9001 Requirements:

8.2 Requirements for products and services
8.3 Design and development of products and services
8.4 Control of externally provided processes, products, and services
8.5 Productions and service provision
8.6 Release of products and services
8.7 Control of nonconforming outputs

PERFORMANCE EVALUATION + *CONTINUOUS IMPROVEMENT*

(Found in Clauses 9, 10)

The goal of an ISO 9001 QMS is to continuously improve products/services, company efficiencies, decrease rework, decrease waste of time/resources, and provide customer satisfaction. If implemented and maintained well, CertFast has witnessed companies get stronger, able to withstand market ups/downs, be prepared for the unexpected, continue to thrive as a business, and grow. To be effective, companies should monitor and evaluate performance.

What does the Standard say about Continuous Improvement?

"The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction." (10.1)

ISO 9001 Requirements:

9 Performance evaluation
9.1 Monitoring, measurement, analysis, and evaluation
9.2 Internal Audit
9.3 Management Review
10 Improvement
10.1 General
10.2 Nonconformity in ISO 9001
10.2 What is Non-conformance?
10.2 Corrective Action
10.3 Continual Improvement

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