

## Questions Covered

- What is ISO 9001?
- What is needed for registration to ISO 9001?
- What are the requirements of ISO 9001:2015?
  - Section 4 - Context of the Organization
  - Section 5 - Leadership
  - Section 6 - Planning for the Quality Management System
  - Section 7 - Support
  - Section 8 - Operation
  - Section 9 - Performance Evaluation
  - Section 10 - Improvement
- What are the next steps?

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4

The requirements of ISO 9001:2015 are described in 7 clauses or sections

Section 4 - Context of the Organization

Section 5 - Leadership

Section 6 - Planning for the Quality Management System

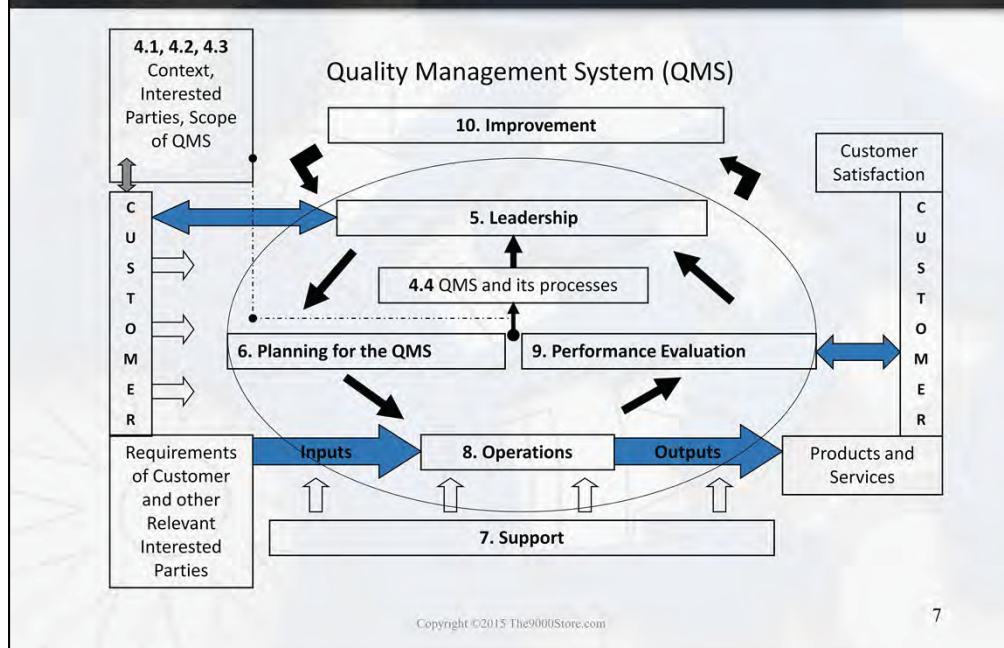
Section 7 - Support

Section 8 - Operation

Section 9 - Performance Evaluation

Section 10 - Improvement

## The Process-Based Model



This example of the process-based model is similar to the one included in the standard (Figure 1).

The seven clauses are all found on the process model.

Leadership, Planning for the QMS, Operations, and Performance evaluation form a cycle that is influenced by the Context of the organization and Support processes aimed at improvement

The most important input to this cycle is customer and other relevant interested parties requirements.

The output of the cycle is customer satisfaction and continual improvement of the quality system.

The standard is organized around this model.

## ISO 9001

- A Quality Management System based on the ISO 9001 standard should be a strategic decision for top management because --
  - A strong and healthy QMS helps to improve the overall performance and becomes an integral part of sustainable development initiatives

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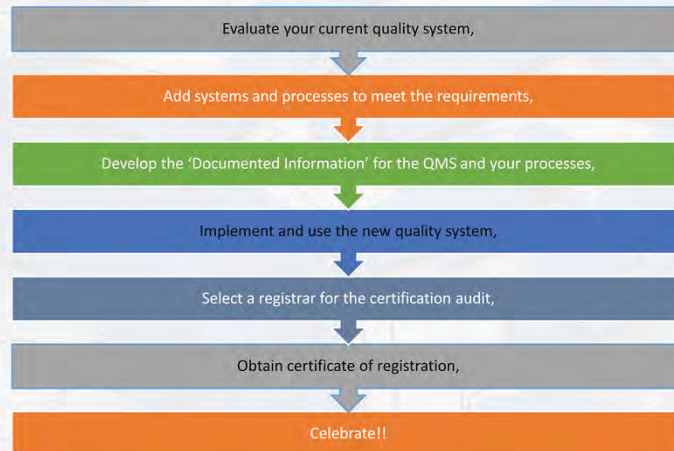
9

The adoption of a quality management system ought to be a strategic decision for an organization.

A robust quality management system can help an organization to improve its overall performance and forms an integral component of sustainable development initiatives.

# What Is Needed for Registration?

To become registered a company must first implement the requirements of ISO 9001:2015



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10

## Evaluate your current quality system:

Many of the requirements of the standard are addressed by practices already in place.

These practices may or may not be described in documented information.

Other requirements of the standard may not be addressed at all and these need to be implemented and documented.

The standard is designed to bring control and consistency to your processes.

Documenting the processes is part of this control.

It helps ensure that people are doing the same thing, to get consistent results.

The documented information may take the shape of a Document Pyramid and include

An Operations Manual:

a top level document that describes briefly what you have in place to meet the standard.

Procedures:

describe what is done, for example the overall procedure for purchasing or training. What is included in the process?

Work Instructions:

detailed documents that describe how to perform a process, for example how to fill out a purchase order etc.

Forms: to provide the evidence that the system is in place.



## 4.2 Understanding the Needs and Expectations of Interested parties

Interested parties may be customers, owners, suppliers, unions, bankers, etc. and to understand their needs and expectations, you must:

- Identify the relevant interested parties, determine, monitor and review their requirements that are Relevant to the QMS.
- Consider their expectations and needs and the impact on the ability to consistently provide products and services that meet customer and statutory and regulatory requirements.

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16

Again -- Remember that for the QMS you only need to consider the issues that are relevant to the QMS.

To completely understand the needs and expectations of interested parties, Your Company identifies the relevant interested parties, determines, monitors and reviews the requirements that are relevant to the QMS.

Their expectations and needs and the impact or potential impact on the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements are considered.

Interested parties may be customers, owners, and people in the organization, suppliers, unions, bankers, partners or society that may include competitors or opposing pressure groups.