Documents are in Microsoft Word for ease of editing

ISO 9001:2015

Quality Management Systems Documentation

Quality Manual / Documented Information

Document No. QM-001

Street Address

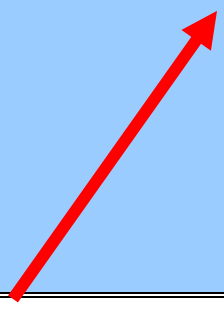
City, State, Zip

Tel,

Cell Phone:

Email:

Web Site:



Blue text throughout the manual highlight areas for customization

Introduction

Your Company developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

Provides general purpose and description of Quality Manual

To fully understand the organization and its nal and internal issues that are relevant and tha lts of the quality management system.

The Quality Management System of Your Company meets the requirements of the international standard ISO 9001:2015. The system addresses the design, development, production, installation, and servicing of the company's products. It incorporates the process approach where consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes.

This process approach provides for the management of the quality system and its processes through the application of a "Plan-Do-Check-Act" methodology and a focus on "Risk-Based-Thinking" leading to the prevention of undesirable outcomes.

The manual is divided into sections that correlate to the Quality Management System sections of ISO 9001:2015. The manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides the documented information with procedures or references for all activities comprising the Quality Management System that ensures the compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or interested parties. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

The manual is approved by a top management representative.

President: _____ Date: _____

Section 01 Scope or the Quality Management System

General

To determine and establish the scope of the QMS, Your Company determined the boundaries and applicability of the QMS and considered the external and internal issues, the requirements of relevant interested parties, and the products and services of the company. The scope is available and maintained as docun ducts and services covered by the QMS.
Your Company applies all the requirements of IS cable within the determined scope of the QMS.

You can search and replace "Your Company" with your own company name

As developed with procedure P-400 for Organizational context, include the scope of your QMS here:

_____

_____

_____

For example, if you are a manufacturer of toys, the scope of your QMS may be:
:
The scope of the Quality Management System includes the major product and service categories associated with the primary functions of manufacturing wooden toys at the North Pole location and distributing the product to children of all ages.

Conformity to ISO 9001:2015 may only be claimed if the requirements determine as not being applicable do not affect the organization's ability or responsibility to ensure conformity of its products and services and the enhancement of customer satisfa
In the event that any requirement is not applicable at Your Company, justification instance where a requirement cannot be applied is documented.

Blue text gives guidance for customization

Your Company has determined that the following requirement(s) is/are not applicable to the operations at this site:

_____.

As determined with procedure P-400, identify the requirement(s) that do not apply and document the justification here:

Related documents are referenced

_____

_____

For example, if you are a manufacturer of toys, a requirement that does not apply may be:
Clause 8.5.5 for post-delivery activities does not apply to the company. Customer feedback has shown that conformity to post-delivery services is achieved with the initial delivery activities.

Section 02 Normative References

There are no normative references.

Section 03 Definitions

Applicable definitions are included in documented procedures and instructions at par 3.0 to enhance the understanding of the process.

1.0 Purpose/Scope

1.1 This procedure describes the process for controlling the procurement process at Your Company to ensure that purchased products and services, and outsourced processes conform to requirements.

1.2 The procedure applies to situations where the control of external providers is required (as defined in par 5.2.1).

2.0 Responsibilities and Authorities

2.1 The Materials manager has the prime responsibility and approval authority for this procedure.

2.2 In support of the Materials / purchasing manager, the Quality team / ISO steering committee is responsible to identify the situations where the requirements for the control of external providers apply.

2.3 Additional responsibilities for the materials manager / quality manager / purchasing department staff / receiving personnel are detailed in relevant paragraphs of section 5.0 below.

3.0 References and Definitions

3.1 References

3.1.1 This document relates to clause 8.4 of the ISO 9001:2015 standard, Control of external providers.

3.2 Definitions

3.2.1 Supplier / Provider: Person or organization such as a producer, distributor, retailer or vendor that provides a product or a service.

4.0 Resources

4.1 None

5.0 Instructions

5.1 In support of the planning procedures P-810 for Operational planning and control, and P-910 for Monitoring, measurement, analysis and evaluation, this procedure addresses the control of external providers.

5.2 The Quality team / ISO steering committee identifies the situations where the requirements for the control of external providers apply.

5.2.1 Control of external providers is required when:

INSERT YOUR COMPANY LOGO/NAME HERE

F-840-003
Provider Corrective Action Request

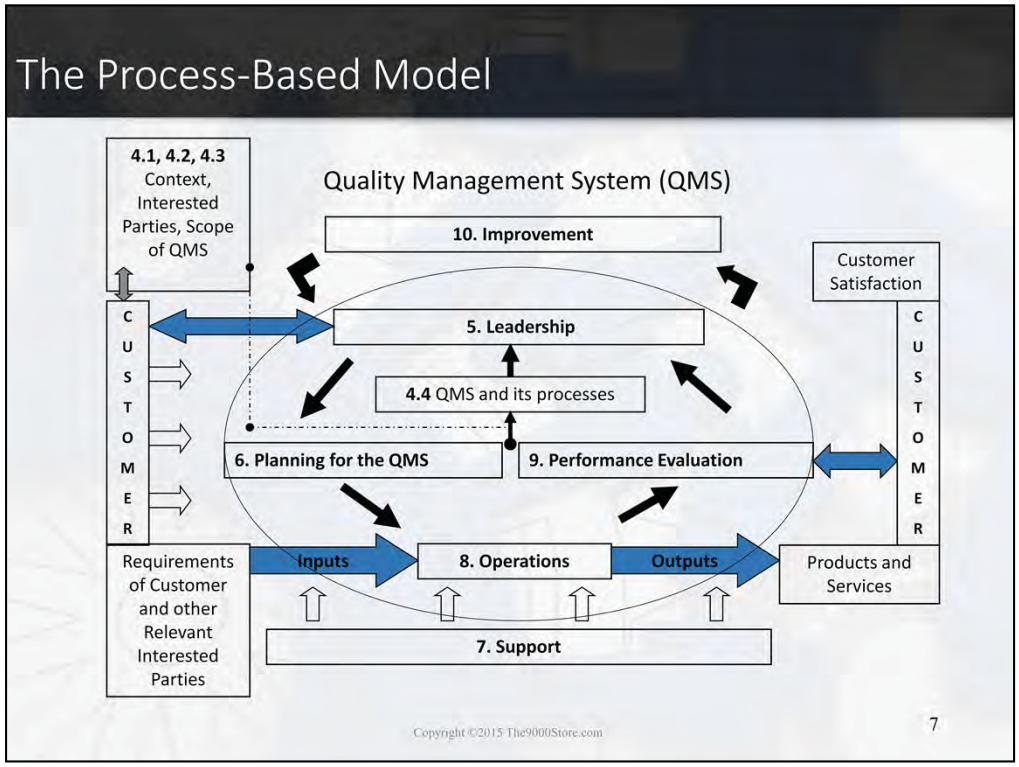
Date:	PCAR No.:

Part / Item:	Part No.:
Dept. / Provider:	Job No. / PO No.:
Qty. Rejected:	Serial / Batch Nos.:

DESCRIPTION OF NONCONFORMANCE	
	Identified By (Signature / Date):

Date:	**DISPOSITION**	
Rework ❒ Use AS-IS ❒ Scrap ❒		
Remarks:		
Approved (Signature / Date):	Approved (Signature / Date):	Approved (Signature / Date):

Due Date:	**CLOSEOUT**
Customer Authorize: Yes ❒ No ❒	Customer Authorization Ref.:
Re-inspected: Yes ❒ No ❒	Inspection Report No.:
Corrective Action:: Yes ❒ No ❒	Corrective Action No.:
Approved (Signature / Date):	Approved (Signature / Date):



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

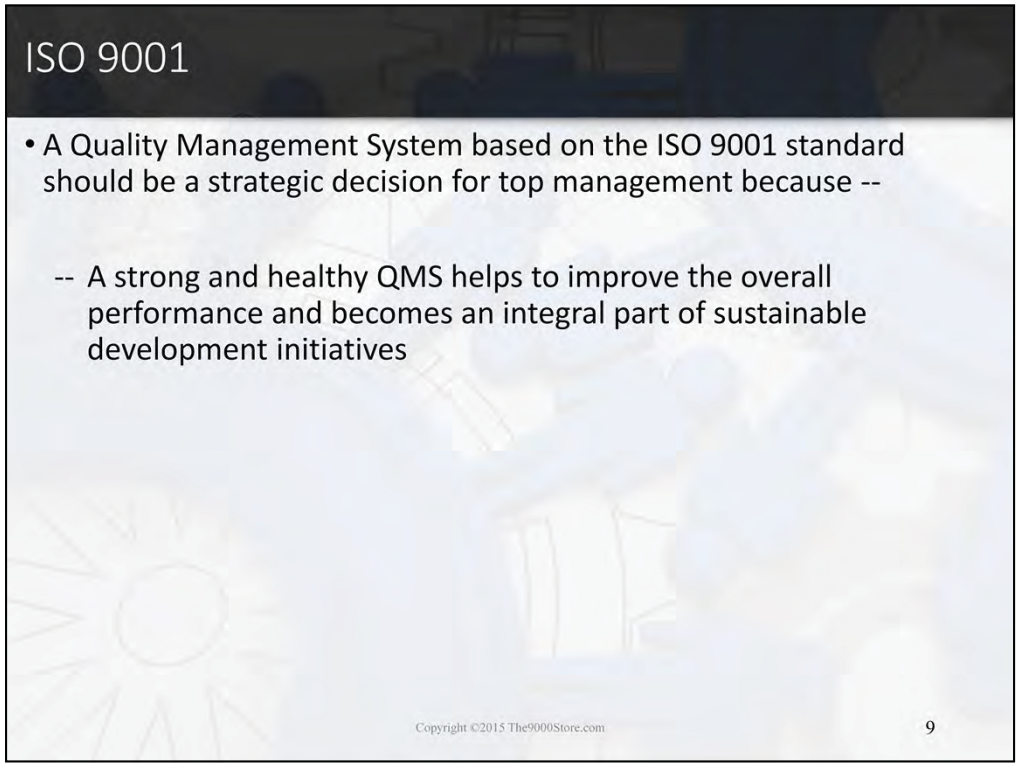
The seven clauses are all found on the process model.

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.



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.

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.

INSERT COMPANY NAME/LOGO HERE

ISO 9001:2015 Quality Management Systems - The Internal Audit Checklist

This checklist is based on the information provided in the ISO 9001:2015 international standard. The checklist is best used by trained and practicing auditors to evaluate or assess Quality Management Systems requirements based on the standard. You will see questions on the checklist that refer to the standard and for each clause provisions are made for additional questions.

The auditors are expected to use a great deal of discretion and therefore must be careful and thoughtful prior to establishing a deficiency against a requirement. Evidence for visible top management leadership, commitment and quality management action must be looked for.

The **bold** numbers and tittles used in the first two columns of the checklist indicate the "Requirements" and may be referred to on nonconformity reports prepared by the auditor.

During assessment of each requirement, auditors record the status of the evaluation by indicating in the right hand column a

Yes - for Acceptable Condition or **No -** for Deficient Condition

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	QUALITY MANAGEMENT SYSTEM	OBSERVATIONS / COMMENTS	STATUS
4	**CONTEXT OF THE ORGANIZATION**		
4.1	**Understanding the organization and its context**		
	Has your company determined the external and internal issues that are relevant to your purpose and strategic direction? Have you considered the relevant issues that affect your ability to achieve the intended results of the Quality Management System (QMS)? How do you monitor and review the information related to the external and internal issues?		

Welcome to ISO 9001:2015

ISO 9001:2015 Resource Center
Our Company is working on becoming ISO 9001:2015 registered. This international standard provides for a Quality Management System that outlines some basic good business practices that we need to have in place.

By implementing a Quality Management System (QMS) that complies with ISO 9001:2015 we will be able to make our company run more efficiently, increase customer satisfaction and communicate to potential customers that we have good quality processes in place.

Surveyed ISO 9001 Registered Companies state that they have:

- Higher customer satisfaction
- Increased profitability because of efficiencies
- Market advantages
- Improved communications
- Higher job satisfaction

What will employees need to do for the ISO 9001:2015 Quality Management System?

First Management will be determining both the internal and external issues that are relevant to the QMS and will identify our "Key Processes".
Those are the processes that affect the quality of our product and our services. Then they will determine how we will control these processes to make sure that we are all doing them the same way, and the best way our organization has identified.

Controlling the process means having documented information for the quality management system, and training employees or finding other or best ways to make sure that the process is done consistently no matter who is doing it. This means that employees may be required to have certain training, or to follow specific work instructions.

Employees will also need to be aware of how their job affects the quality of our products and customer satisfaction.

ISO 9001 Highlights: Things that you will be hearing about as we proceed with this project….

Our Quality Policy
We will identify our Quality Policy, and will be communicating it to all employees. It is important that all of us are aware of what this statement says about our company's vision is for quality and for meeting customers' expectations.

Registration Audit
To become ISO 9001:2015 registered, we will be audited by an independent Registrar. This Registration Audit will be done after we have set up processes to meet all the requirements of ISO 9001. The Registrar will send an auditor or audit team to come in to our facilities and evaluate the processes we have in place.
They will check to see if the processes meet the requirements of the standard, and to see if we are following the processes. If everything looks good, we will be recommended for registration and be recognized globally!

Watch for our next newsletter for more introduction to ISO 9001:2015, what it will mean to you and your coworkers.