

# ISO 9001:2008 Quality Manual & Procedures Package

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## Abstracts

## **GENERAL INFORMATION ABOUT ISO 9001**

The ISO 9000 is the world's most recognized quality management standard. The ISO 9000 family addresses various aspects of quality management and contains some of ISO's best known standards. The standards provide guidance and tools for companies and organizations who want to ensure that their products and services consistently meet customer's requirements, and that quality is consistently improved.

#### ISO 9001:2015

ISO 9001 is the world's most widely recognized Quality Management System (QMS). It belongs to the ISO 9000 family of quality management system standards and helps organizations to meet the expectations and needs of their customers, amongst other benefits.

An ISO 9001 quality management system will help you to continually monitor and manage quality across all operations, and outlines ways to achieve, as well as benchmark, consistent performance and service. Internationally, it is the quality system of choice.

ISO 9001:2015 sets out the criteria for a quality management system and is the only standard in the family that can be certified to (although this is not a requirement). It can be used by any organization, large or small, regardless of its field of activity. In fact, there are over one million companies and organizations in over 170 countries certified to ISO 9001.

This standard is based on a number of quality management principles including a strong customer focus, the motivation and implication of top management, the process



approach and continual improvement. Using ISO 9001:2015 helps ensure that customers get consistent, good quality products and services, which in turn brings many business benefits.

As an ISO 9001 certified organization you will have implemented Quality Management System requirements for all areas of the business, including:

Facilities People Training Services Equipment

ISO 9001 certification is suitable for all sizes and types of organizations and is well established around the world as an invaluable Quality Management System standard. It is suitable for organizations in all industry sectors and will help your organization to improve management processes to compete locally and/or globally.

The process encompasses the entire organization and requires senior management buyin, it is not just a function of the Quality Department. To achieve ISO 9001 certification your organization needs to demonstrate that it can meet the regulatory requirements and apply the system effectively to be of real benefit to your customers.

Sector-specific applications of ISO 9001

ISO has a range of standards for quality management systems that are based on ISO 9001 and adapted to specific sectors and industries. These include:

ISO/TS 29001 – Petroleum, petrochemical and natural gas industries

ISO 13485 - Medical devices

ISO/IEC 90003 - Software engineering



ISO 17582 - Electoral organizations at all levels of government

ISO 18091 - Local government

#### **BENEFITS OF ISO 9001**

ISO 9001 Certification will provide maximum benefit to your organization if it approaches ISO 9001 implementation in a practical way. This will ensure that the Quality Management Systems that are adopted, work to improve the business and are not just a set of procedures that your employees will find hard to manage.

By adopting an approach that starts out to implement more efficient working practices and focuses on the business objectives of the organization, you will achieve a system that will help and support your staff, and improve your levels of customer satisfaction.

Whether you use an external assessor or allocate an internal resource to carry out the initial assessments, you will need to ensure that they have buy-in from senior management, so that all areas of the organization are aware of the importance of the ISO 9001 Certification process.

ISO 9001 Certification is not just suitable for large organizations but also small businesses that will benefit from adopting efficient Quality Management Systems that will save time and cost, improve efficiency and ultimately improve customer relationships.

Some of the benefits to your organization:

Provides senior management with an efficient management process

Sets out areas of responsibility across the organization

Mandatory if you want to tender for some public sector work

Communicates a positive message to staff and customers

Identifies and encourages more efficient and time saving processes

Highlights deficiencies



Reduces your costs

Provides continuous assessment and improvement

Marketing opportunities

Some of the benefits to your customers:

Improved quality and service

Delivery on time

Right first time attitude

Fewer returned products and complaints

Independent audit demonstrates commitment to quality

#### **CERTIFICATION TO ISO 9001:2015**

Checking that the system works is a vital part of ISO 9001:2015. It is recommended that an organization performs internal audits to check how its quality management system is working. An organization may decide to invite an independent certification body to verify that it is in conformity to the standard, but there is no requirement for this. Alternatively, it might invite its clients to audit the quality system for themselves.

An ISO 9001 Quality Procedures Manual simplifies the task of complying with the ISO 9001 standard. It can be written in a way that the quality policies and procedures can be generalized for any business.

Implementing the ISO 9001 Quality Management System can serve as a business improvement tool. Frequently the ISO standard is perceived as a checklist item; Get ISO 9001 Certified; Done. The real goal of ISO 9001:2015, however, is continual improvement of the organization. Embracing the concepts of ISO 9001 can enhance an organization in several ways.



There really is no single 'right' format or contents for what an ISO 9001 quality manual must look like. Many people still insist loudly and emphatically that there is, and that an ISO 9001 Quality Manual Should Always Look Like This, contain these exact headings, etc. They are all wrong.

All you have to do is meet the requirements of the Standard, so do it in a way that suits you. And that includes the 'quality manual': it depends entirely on what is suitable for you and what's needed for your company in your situation.

Putting Together an ISO Quality Management System

According to the needs of the organization, the components of the ISO 9001 Quality Procedures Manual consists of filling up the following:

#### QMS Scope

QMS Scope, consists of defining the requirements of relevant interested parties, the types of products and services covered by the QMS, and provide justification for any exclusions to requirements of ISO 9001 that the organization determines is not applicable to the scope of its quality management system.

Note: Exclusions to ISO 9001 may only be claimed if they do not affect the organizations ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

#### **Quality Policy**

Quality Policy, must be appropriate to the purpose and context of the company. It ties in with and provides a framework for the Quality Objectives, includes a commitment to satisfy requirements, and a commitment to continual improvement of the QMS.

#### **Quality Objectives**

Quality Objectives, are derived from the Quality Policy, are measurable, and communicate to interested parties the effectiveness of the QMS. As objectives, they provide a basis for planning that at a minimum includes: Who, will do What, by When, requiring What resources, and How will results be evaluated.

#### QMS processes



QMS processes are those necessary for the QMS. Each QMS process shall list:

the inputs and outputs expected,

the sequence and interaction of these processes with each other,

measurable process criteria (or control method),

resources required by the process,

responsibility for the process,

process risks,

how the process will be evaluated, and

opportunities for improvement.

**ISO** Quality Manual

Next, you can create a Quality Manual. A Quality Manual explains the "scope" of your system. It is not required anymore, but it helps to explain what the boundaries are (scope), your Quality Policy, Quality Objectives, and QMS Processes.

There is a new term "Documented Information" that has replaced required procedures. There are 24 quality procedures in the new and improved ISO 9001:2015 QMS. Quality procedures that are included are ones that many organizations consider important or critical (e.g., Internal Auditing, Corrective Action). Those procedures are modeled on the Deming Cycle — they have a Plan, Do, Check, and Act phase.

#### ISO 9001 Documented Information

You specify what you need. If your need work instructions then create them. If you workforce is quite skilled and your product is does not vary a lot, then maybe you just need training material. It's your decision.

An important concept to understand is that procedures are only one way to document



processes, and the ISO standard recognizes that. Processes can be documented by Work Instructions, Visuals Aids, or training materials. The real requirement by ISO is that key business processes are understood and consistently carried out.



## Contents

It contains the following areas:

### **SECTION 5:**

- Management Responsibility
- 5.1 Management commitment
- 5.2 Customer focus
- 5.3 Quality policy
- 5.6 Management review
  - 5.6.2 Review input
  - 5.6.3 Review output

AP-821-A

Monitoring, Measuring and Analysis of Customer Satisfaction

#### 1.0 PURPOSE

#### 2.0 RESPONSIBILITIES

## **3.0 DEFINITIONS**

#### 4.0 EQUIPMENT/SOFTWARE

#### **5.0 INSTRUCTIONS**



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