

**ISO 9001 : 2015 Quality Management System  
Beginners' Guide  
PREVIEW**

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## Introduction

ISO 9001 defines the criteria for a Quality Management System and is the only standard in the family that can be audited against with the goal of voluntary compliance or to become 3rd party registered. In fact, there are over one million companies and organizations in over 170 countries certified to ISO 9001. All the requirements of ISO 9001 are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides. The ISO 9001 standard is based on a series of ISO 9000 standards:

- ISO 9001 – defines the requirements of a quality management system
- ISO 9000 – covers the basic concepts and language
- ISO 9004 – focuses on how to make a quality management system more efficient and effective
- ISO 19011 – provides guidance on internal and external audits of quality management systems

The standard is based on **seven Quality Management Principles**, including a strong customer focus, the motivation and implication of top management, the process approach and continual improvement.

**These Quality Management Principles are identified as follows:**

1. Customer focus
2. Leadership
3. Engagement of people
4. Process approach
5. Improvement
6. Evidence-based decision making
7. Relationship management

Complying with ISO 9001 ensures customers get consistent, good quality products and services, which in turn brings many business benefits.

## Process Approach

**Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system' –**

The process approach is a management strategy which incorporates the plan-do-check-act cycle and risk-based thinking. It means that processes are managed and controlled. It also means that we not only understand what the core processes are, but we also consider how they fit together.

ISO 9001:2015 employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. This means the organisation needs to:

1. determine required process inputs and expected outputs,
2. assign responsibilities and authorities for processes,
3. identify risks and opportunities for processes, and plan to address these.

### **Risk-based thinking**

The revised ISO 9001 standard has moved away from what it called "preventive action" towards a "risk-based approach". Preventive action was found to be lacking when it came to driving change and continuous improvement. The risk-based approach is likely to be much more effective in allowing organisations to become stronger, fitter businesses.

#### **Taking a risk-based approach means:**

- **Determining the risks** and opportunities
- **Planning actions** to address them
- **Implementing them** in a **quality management system**
- **Evaluating** their effectiveness

All this ensures your organisation is proactive rather than reactive, preventing potentially damaging events and promoting improvement. Once a management system is risk-based, preventive action is automatic. Though we commonly understand risk to be negative, risk-based thinking has a more positive slant in that it provides opportunities for improvement and enables businesses to make strategic decisions.

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