

INTRODUCTION TO ISO9001: 2015

OVERVIEW

ISO 9001:2015 outlines the requirements for a quality management system (QMS) to consistently deliver quality products and services to its customers and stakeholders. It also acts as an excellent foundation for the implementation of a range of other management standards.

A QMS is a group of operational processes that;

- Align with the organisation's goals
- Encompass the policies, procedures, documentation, and resources required to achieve set goals

A certified QMS may help organisations to;

- Meet customers quality requirements.
- Meet regulatory requirements
- Enhance customer satisfaction
- Achieve continual improvement of performance

Organisations, of any size and scope of work, can adopt a QMS.

There are over one million companies and organisations in more than 170 countries certified to ISO 9001.

ISO 9001 sets out the criteria for a quality management system.



BENEFITS

BENEFITS OF ISO 9001*

Better products and services

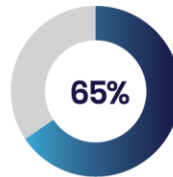


Improving your products and services

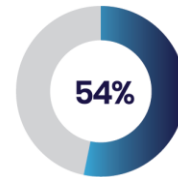


Reducing the likelihood of mistakes

Better for business



Inspiring trust in your business



Increases your competitive edge



Attracting new customers

EXTERNAL

- ISO 9001 certification is an excellent way for regulatory bodies to ensure quality control throughout supply chains
- Compliance for tender applications
- Demonstrate objective proof that your organisation attaches great importance on quality
- Commitment to gaining certification increases the confidence of external stakeholders
- Achieve higher operating efficiency thereby increasing capacity and process cycle times
- Increase the quality of your products and services with fewer errors
- Demonstrate to all stakeholders that customer satisfaction is at the core of the business
- Give a positive company image and raise above competitors in a specific market

INTERNAL

- Ensures well-defined processes, communication structures, tasks and responsibilities flow throughout the entire organisation
- Increase staff engagement in operational processes and organisational objectives
- Improve workplace atmosphere and culture
- Detect and identify problems timeously and enable quick responses to avoid the same mistakes in the future



HOW TO MEET THE ISO9001 REQUIREMENTS

TERMS AND DEFINITIONS IN THAT STANDARDS

ORGANISATION

An organised group of people with a particular purpose, such as a business or government department.

INTERESTED PARTY (STAKEHOLDER)

A stakeholder is a party with interests in a company and can either affect or be affected by the business. A person or organisation involved in or perceives itself to be affected by activities and actions taken by another organisation. EG. Customers, suppliers, contractors, local community, government, etc.

TOP MANAGEMENT

An individual or group of individuals who manage an organisation at the highest level.

Terms and Definitions

All terms and definitions related to ISO 9001:2015 are in the standard. However, ISO 9001:2015 does not provide any explanations for the words used. It is necessary to understand the terms before starting to implement the requirements of the standard.

Here are some of the most important terms and definitions.

CONTEXT OF THE ORGANISATION

Internal and external factors that affect the purpose, objectives, performance, and sustainability of an organisation.

Internal factors include

- Values
- Culture
- Knowledge
- Performance

External factors include

- Legal
- Technological
- Competitive
- Market
- Cultural
- Social
- Economic environment

PROCESS

A series of actions or steps taken to achieve a particular end. A sequence of activities that use inputs to deliver an intended result.

PROCEDURE

A procedure defines ways to execute an activity or a process. Procedures can be documented or not.

QUALITY

Quality is the difference between a customer's expectations and the customer's perception of what has been received.

NONCONFORMITY

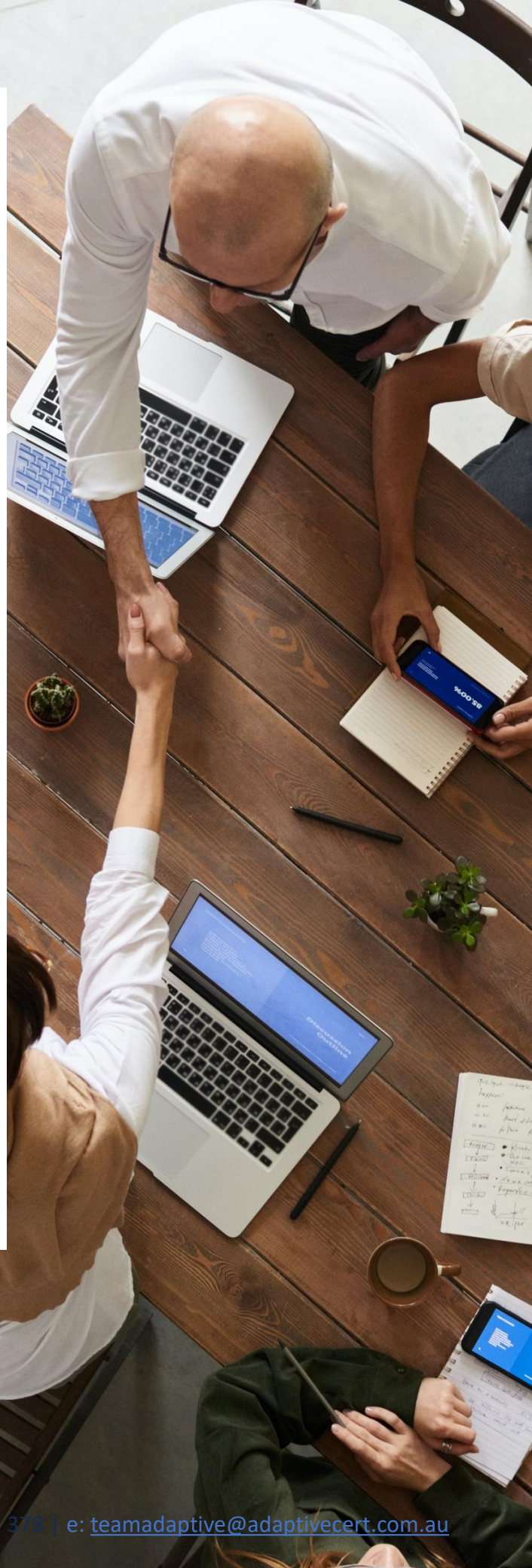
Nonconformity is the failure to meet a requirement.

RISK

Risk is the effect of uncertainty on objectives. An effect is a positive or negative difference from what is expected.

EFFECTIVENESS

Effectiveness is the level of success in achieving or producing a desired result.





THE PROCESS FLOWCHART

The process flowchart is a graphical overview of all processes within an organisation.

Flow charts aid in the management of operations and provide the framework to track process performance. By creating a process flowchart, organisations can satisfy the requirements of clause 4.4 of ISO 9001:2015.

A process is a set of interrelated or interacting activities that transforms inputs into outputs. These activities require allocation of resources such as people and materials. The process approach is a way of applying processes as a system. A system is a defined network of processes and their interactions.

Primary process groups

- Management processes
- Operational processes
- Supporting processes

Management processes

- Planning and providing resources for operational and supporting processes
- Monitoring and measuring the performance of the Quality Management System.
- Ensure products or services achieve customer satisfaction

Operational processes

- Core processes, directly related to creating or delivering a product or service.
- Placed in the centre of the process flowchart, making up the "Do" of the Plan/Do/Check/Act cycle.
- Have a customer focus ensuring that products and services achieve customer satisfaction

Supporting Processes

- Provide support for the correct functioning of the management and operational processes.
- Crucial process enabling other processes to function effectively.

QMS

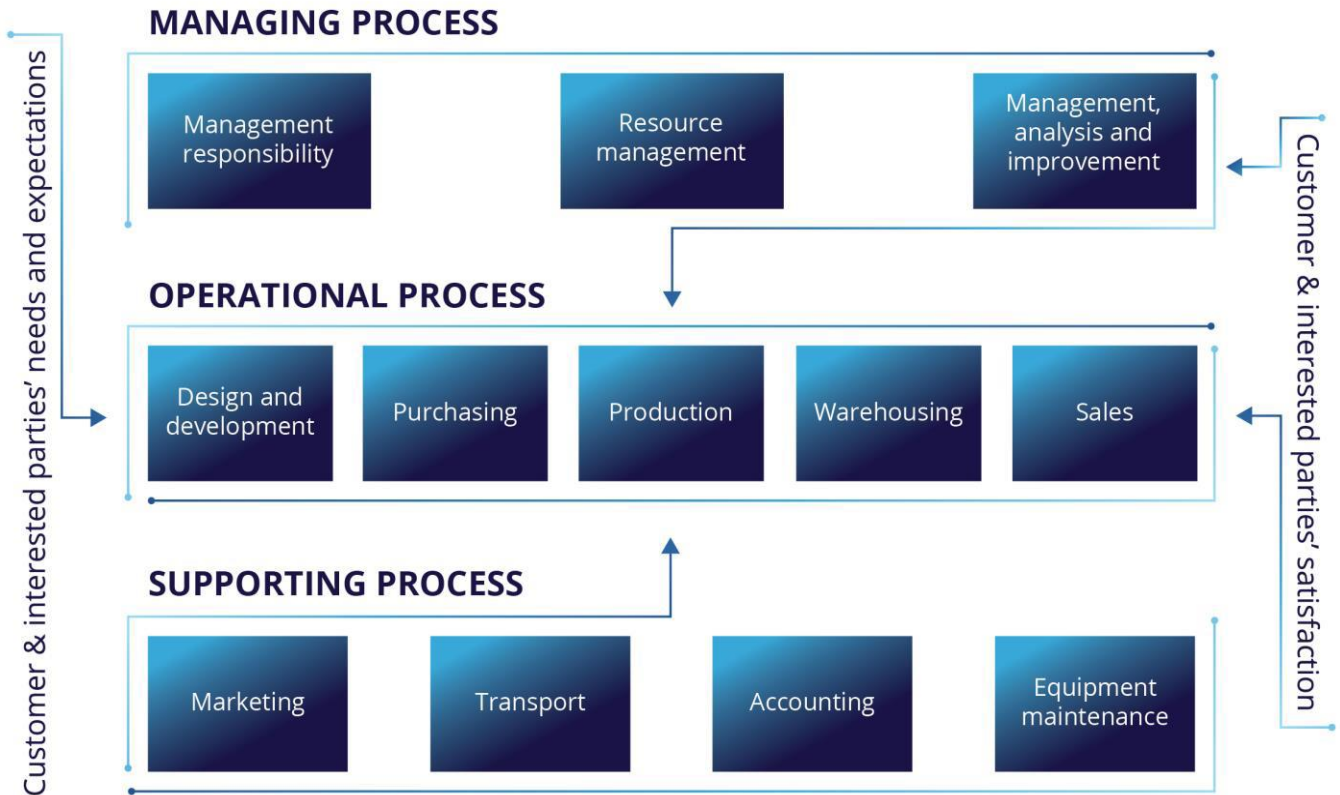
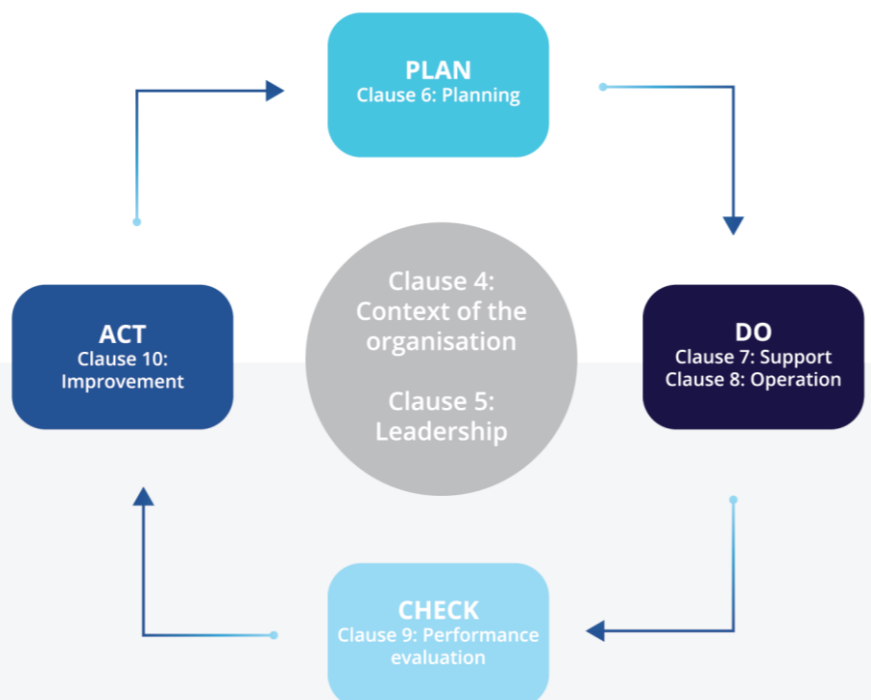


Figure 1: Process map

PLAN-DO-CHECK-ACT CYCLE





PLAN-DO-CHECK-ACT (PDCA) CYCLE

The core of many management system standards

PLAN

- Understand the context of the organisation
- Understand the needs of parties interested in the QMS (4.1 & 4.2), then use to define the scope of the QMS and the QMS processes (4.3 & 4.4)
- Define the organisational roles and responsibilities
- Establish a quality policy to give the overall QMS a focus (5.1, 5.2 & 5.3)
- Identify and address risks and opportunities of the QMS
- Setting and planning for quality objectives and changes to support continual improvement (6.1, 6.2 & 6.3)
- Identify and implement the support structures, including resources (7.1), identifying competence (7.2), awareness (7.3), communication (7.4) and to set the processes for creation and control of documented information (7.5)

DO

- Identify the Product or service requirements (8.2)
- Develop designs (8.3)
- Place controls on externally provided processes, products, and services (8.4)
- Carry out the process of producing the product or service (8.5 & 8.6)
- Address any non-conforming products or services need to (8.7)

CHECK

- Ensure that processes are functioning as intended
- Monitor, measure, analyse and evaluate products or services
- Ensure processes are adequate and effective
- Ensure that customer satisfaction is being met (9.1)
- Conduct Internal Audit (9.2) of the processes
- Conduct Management Review process (9.3)

ACT

- Act for improvement (10.1 & 10.3)
- Address nonconformity and Corrective Actions (10.2)



ISO 9001 REQUIREMENTS

The structure of the ISO 9001:2015 standard splits into 10 sections (clauses).

- 1 to 3 are introductory
- 4 to 10 contain the requirements for the Quality Management System

SEVEN PRINCIPAL CLAUSES OF ISO9001

Clause 4: Context of the organisation – Understand your organisation to implement a QMS.

This section covers requirements for;

- Identifying internal and external concerns
- Identifying interested parties and their expectations including regulatory requirements
- Defining the scope of the QMS
- Identifying your processes and how they interact

Clause 5: Leadership – Top management to be instrumental in the implementation of the QMS.

Top management needs to demonstrate a commitment to the QMS by;

- Ensuring customer focus
- Defining and communicating the quality policy
- Assigning roles and responsibilities throughout the organisation

Clause 6: Planning – Top management must plan for the ongoing function of the QMS.

- QMS Risks and opportunities assessments made
- Identification of Quality objectives for improvement
- The organisation must make Plans to accomplish objectives

Clause 7: Support – The management of all resources supporting the QMS. The necessity is to manage, monitor and measure all resources, including;

- Human resources
- Buildings and
- Infrastructure
- Working environment
- Organisational knowledge.

Organisations must also consider;

- Resource competence
- Awareness
- Communication
- Control of documented information (processes, records, etc.).

Clause 8: Operation – The operational requirements of planning and creating a product or service.

Clause 8 covers the requirements for;

- Planning
- Product requirements review
- Design
- Controlling external providers,
- Creating and releasing the product or service
- Controlling nonconforming process outputs

Clause 9: Performance evaluation – The requirements needed to ensure that a QMS is monitored and is functioning well, including;

- Monitoring and measuring your processes
- Assessing customer satisfaction
- Internal audits
- Ongoing management review of the QMS

Clause 10: Improvement – The requirements needed to improve the QMS over time continually by;

- Assessing process nonconformity
- Taking corrective actions for process



HOW TO PLAN YOUR CERTIFICATION PROJECT

- PROJECT PLAN

A management system be?

 - Fit for Purpose
 - Simple, easily understood, and accessible
 - Effective
 - Able to integrate with other management systems.

TASK	ACTIONS	NOTES
1. Gap Analysis	Undertake Gap Analysis	
2. System Planning	Identify Interested Parties	
2. System Planning	Operational Risk Assessment	
2. System Planning	Quality Manual – Planning	
2. System Planning	Quality Manual – Support	
2. System Planning	Quality Manual – Operations	
2. System Planning	Quality Manual – Improvement	
2. System Planning	Quality Risk Analysis	
2. System Planning	Branding/design of completed QMS Manual	
3. Draft System Documents	Quality Policy	
3. Draft System Documents	Management System Registers	
3. Draft System Documents	Management System Procedures	
4. Implementation Planning	Plan implementation	
4. Implementation Planning	Set objectives and targets	
4. Implementation Planning	Compile legal and other requirements	
5. Awareness Training	Define awareness requirements	
5. Awareness Training	Carry out awareness training	
6. Implementation Activities	Plan training requirements and activities	
6. Implementation Activities	Implement training requirements and activities	
7. Review	Internal audits	
7. Review	Management Review Meeting	
8. Stage 1 Audit	Engage certification company for stage 1 audit	
8. Stage 1 Audit	Complete stage 1 audit	
9. Address Gaps	Address any gaps raised at stage 1 audit	
10. Stage 2 Audit - Certification	Undertake stage 2 audit and receive certification	