



FACT SHEET

ISO 9001:2015 QUALITY MANAGEMENT SYSTEMS

What does your business need to do?

Being certified to ISO 9001:2015 Quality Management Systems is what most businesses choose to do. This is because it is the one that impacts across business operations through a systematic approach to achieving customer requirements.

Importantly, it creates a “closed loop” so that the business learns quickly for its mistakes and reduces the potential that they make the same mistakes again. It is structured on the simply but effective improvement loop:

Plan – planning to deliver for customers and the business.

Do – implement the plan in a systematic way.

Check – check that the system is working.

Act – fix issues as well as identify and implement improvements.

It also ensures that business is conducted in a consistent and systematic way to give greater certainty on the results achieved.

A well-designed quality system will also give you a greater sense of control and improved data to know how the business performing at any point in time.

The clauses of the ISO9001:2015 are explained below and gives you a good idea of what you needs to have in place to achieve certification.

Clause 4.1 - Understanding the Organisation and its Context

The business demonstrates that it understands, monitors and reviews the internal and external factors that influence the Quality Management System.

Clause 4.2 - Understanding the Needs and Expectations of Interested Parties

The business demonstrates that it understands monitoring and review of the key groups of people (e.g. customers, suppliers, regulators, staff) that influence our business and Quality Management System.

Clause 4.3 - Determining the Scope of the Quality Management System

The scope of the Quality Management System is documented

Clause 4.4 - Quality Management System and its Processes

Risks and opportunities have determined the Quality Management System processes and you know how the system is working including:

- The inputs and outputs of each process.
- How the processes relate to one another.
- The operation and control of each process.

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- How the processes relate to one another.
- The operation and control of each process.
- Resources required for each process.
- Documents to confirm the processes are operating as intended.

Clause 5.1 – Leadership, Commitment and Customer Focus

Top management are committed to the system as demonstrated by:

- Alignment with strategy.
- Communication and integration into business operations.
- Resources being adequate to operate the system.
- Regular reviews of effectiveness and ongoing system improvement.
- Compliance with statutory and regulatory requirements.
- Determine and address risk and opportunities to improve product/services.
- Ongoing emphasis on enhancing customer satisfaction.

Clause 5.2 – Quality Policy

Top management has a Quality Policy that:

- Is appropriate to the business context and strategy.
- Commits to continual improvement.
- Provides a framework for setting quality objectives
- Is communicated, understood and applied.
- Available to interested parties.

Clause 5.3 – Organisational Roles, Responsibilities and Authorities

The business has assigned responsibilities and authorities to roles that:

- Ensure the system meets ISO 9001:2015.
- Ensure processes deliver the outputs.
- Report on system performance and opportunities for improvement.
- Promotion of customer focus.
- Ensure integrity of the system when changes are made to it.

Clause 6.1 - Actions to Address Risks and Opportunities

The business has understood the risks and opportunities and has implemented plans to:

- Ensure the system achieves what is intended.
- Desirable outcomes are more likely.
- Undesirable outcomes are reduced or eliminated.
- Improvements are identified and acted upon.



Clause 6.2 - Quality Objectives and Planning to Achieve Them

The business has developed, communicated and regularly reviews its quality objectives. These objectives are consistent with the policy as well as being measurable and monitored for success.

The business has developed and implemented plans to achieve the objectives with actions, resources, responsibility, date of completion and evaluation criteria.

Clause 6.3 - Planning of Changes

The business ensures that any changes maintain the integrity of the system, are adequately resourced and responsibilities and authorities have been aligned to the changes.

Clause 7.1 - Resources

The business has determined and provided the people, infrastructure and environment to implement and improve the system and ensure products/services meet customer requirements.

The business has determined, provided and maintained (including calibrated when required) its monitoring and measurement equipment used in the assessment of whether the product/service meets customer requirements.

The business has determined, maintained and made available the knowledge required to operate its processes and ensure its products/services meet customer requirements.

Clause 7.2 - Competence

The business has determined the competencies (qualifications, skills and experience) required for each role. The business recruits new or trains existing staff to ensure these competencies are available and evaluate the effectiveness of recruitment or training.

Clause 7.3 - Awareness

The business has ensured that staff and suppliers understand the quality policy and objectives, their role within the system and the impact upon customer of not getting things right.

Clause 7.4 - Communication

The business understands what system information is communicated to whom, the person responsible for each communication, how they will communicate and when it will be communicated.

Clause 7.5 - Documented Information

The business has the documented information required by the standard and the documented information necessary to understand the effectiveness of its system. This includes a procedure that covers how system documents are created, reviewed and approved for use.

The business also has documented how it:

- Provides access
- Protects it (e.g. log on and back ups)
- Stores it (e.g. filing system)
- Determines what is retained and for how long (how it is disposed of)
- Legislation, regulations, standards, codes and other external requirements are made available and kept up to date.

Clause 8.1 Operational Planning and Control

The business has planned, implemented and controlled the processes including:

- Requirements for products/services.
- Acceptance criteria for processes and products/services.
- Determined resource needed to meet requirements.
- Implemented controls to ensure processes deliver against requirements.
- Retain documents that prove processes are performing as intended and products/services meet customer requirements.
- Any changes to the system are planned and controlled.
- Outsourced processes are controlled.



Clause 8.2 – Requirements for Products and Services

The business communicates with its customers to:

- Inform on product/services.
- Handle enquiries and orders.
- Get customer feedback including handling of customer complaints.
- Handle and control customer property.

The business determines, reviews and confirms in writing requirements related to its products/services including:

- Those stated by the customer.
- Those implied by the intended use of the product/service.
- Any statutory or regulatory issues.
- Delivery of the product/service.
- After sales services.
- Manage any changes including documenting them.

Clause 8.3 – Design and Development

The business has a design and development process that is appropriate to the complexity of the task.

This process takes account of the internal and external resources required, and spells out the controls between each point in the process.

It also sets out the involvement of customers in the processes and the provision of the products/ services including after sales service.

The business ensures that its process is implemented with review, verification, and validation evident in the following elements of the design and development process:

1. Design and development inputs including functional, performance and compliance requirements, information from previous activities and the potential consequences of failure.
2. Design and development outputs including specifying the characteristics of the product/ service that are essential for their intended purpose, acceptance criteria and the use of monitoring and measuring of product/service (or part of it).
3. Design and development changes are controlled and records retained of these changes including reviews, authorisation and actions to prevent adverse impacts.

Records are kept that prove that the design and development requirements have been met.



Clause 8.4 – Control of Externally Provided Processes, Products and Services

The business has very clear means of controlling external providers that reflects the importance of their input to meeting product/service requirements and enhancing customer satisfaction. Specifically the business needs to ensure that:

- The external providers remain within control of the quality management system.
- The controls used for external providers are defined, monitored, verified and reviewed for effectiveness.
- Requirements of external providers are clearly communicated to them including approvals (products, services, methods and processes) and the control and monitoring of the external provider performance.

Clause 8.5 – Production and Service Provision

The business controls its production by having the means to provide:

- Documented product/service characteristics and results to be achieved.
- Effective monitoring and measuring resources.
- Evidence that its processes produce the intended results.
- Proof of product/service release, delivery and ongoing service activities.
- The means to identify and trace its products/services.
- Protection of the property of customers and suppliers.
- Post delivery activities are determined taking account of the statutory obligations, intended use and lifecycle of the product/service and customer feedback.
- Control of any changes to the product/service to ensure they meet requirements.



Clause 8.6 - Release of Products and Services

The business is able to determine through the production process that its product/service meets requirements.

Records are retained of the product/service verification and who approved that it met the criteria specified requirements.

Clause 8.7 – Control of Non conforming Outputs

The business must have a way of identifying, controlling and fixing or excluding from delivery products/services that do not meet requirements.

Records must be kept that demonstrate actions taken and by whom when a product/service was identified as not meeting requirements. If the product/service is fixed and released for delivery there is a record of who authorised its release and why they did so.

Clause 9.1 – Monitoring, Measurement, Analysis and Evaluation

The business must have ways that it collects, analyses and reviews data on key aspects of business operations including:

- Product/service characteristics important to acceptance criteria.
- Customer satisfaction.
- Performance and effectiveness of the quality management system.
- Planning effectiveness including actions on risks and opportunities.
- Performance of suppliers.

Clause 9.2 – Internal Audit

The business must conduct its own internal audit and have a document that describes:

- Audit criteria including standard and you system requirements.
- Calendar of audit dates.
- Objectivity, impartiality and competency of the auditor.
- Reports are available for review by management.
- How issues are promptly fixed.

Clause 9.3 – Management Review

The business conducts at least an annual management review of the quality management system. The standard is very specific about the inputs:

- Customer satisfaction and other feedback.
- Identifying and fixing problems.
- Results form measurement/analysis.
- Audit findings.
- Performance of external providers.
- Adequacy of resources.
- Effectiveness of risk/opportunities plans.
- Ideas for improvement.

The standard is also very specific about the outputs of the review and includes improvement plans, the needs for changes to the quality management system and any change required to resources.

Clause 10 – Improvement

The business can identify when a product/service does not meet customer requirements. The means to quarantine it until it can either be disposed of or fixed. If it is fixed, then proof that it has been and now meets the requirements.

The business can identify when a quality management system process has not been implemented as expected.

When a product/service or process does not meet requirements, the business needs a logical process for ensuring that the issues are fixed and the chance of it happening again are eliminated or significantly reduced. The characteristics of this corrective action process includes:

Review and analysis including the how common the issue is.

- The underlying cause (root cause) of the issue.
- Identify actions to fix the issue.
- Implement actions to fix the issue.
- Review the effectiveness of the action to fix the issue.

The business needs to be able to prove that it has implemented a logical procedure with these characteristics and also makes use of it.

The business needs to be able to demonstrate that it is continually improving its quality management system to minimise rework and maximise customer satisfaction.