



# ISO 9001

## QUALITY

# MANAGEMENT MANUAL


A hand is shown interacting with a futuristic digital interface. The interface features a central circular graphic with the text 'QUALITY ASSURANCE' in white. Surrounding this are several hexagonal icons and labels: 'STANDARD', 'MANAGEMENT', 'SERVICE', 'PROCESS', 'CONTROL', and 'CUSTO'. Other icons include a checkmark, a thumbs up, a gear, a person, a group of people, a padlock, and a document. The background is dark blue with a glowing blue arc at the top.

**QUALITY  
ASSURANCE**

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Any changes to products, services, processes, procedures or legislative requirements are to be reflected in the quality management manual and the revision details are to be recorded below.



# 1. INTRODUCTION

Insert Your Company is a insert what your company does company operating from insert head office. We have developed and implemented a quality management system that uses AS/NZS ISO 9001, Quality Management Systems – Requirements as the framework for structuring our core business processes. This empowers our organization to document and improve our practices to better satisfy the needs and expectations of our customers, stakeholders and other interested parties.

The management and staff of Insert Your Company are committed to continually improving our products and services and the effectiveness of our quality management system. The results of management reviews, customer feedback, audits, inspections and testing all contribute to our continual improvement process.

Please refer to our section 13 Correlation Matrix for an overview of our management system processes and our application to the ISO 9001 Standard. Also, refer to section 4.4. Quality Management System and its Processes to review our management system approach.

## 1.1. Company Details

Company Name:	Insert details
ABN:	Insert details
Head Office Address:	Insert details
Postal Address:	Insert details
Phone:	Insert details
Fax:	Insert details
Email:	Insert details
Website:	Insert details

## 1.2. Quality Mission Statement

Insert Your Company is a professional corporate business with family values. One of our business objectives is to provide a quality of service which sets the benchmark for the industry in Australia, with the intention of being the industry leader in insert what your company does.

Our general quality objectives include:

• Ensuring the delivery of efficient and professional service of a quality that consistently meets or exceeds our client's expectations.

• Ensuring a strong culture of quality across the organization, where key performance indicators are measured and interested parties' needs and expectations are understood and achieved.

- Ensuring that the business is efficient, flexible and proactive.
- Ensuring, as far as practicable, a safe and rewarding working environment for all our personnel.
- Encouraging personnel to reach their potential.



- Proactively marketing our products and services to achieve year on year growth in turnover.
- Striving for continual improvement.
- Keeping accurate, centralized and consistent accounts to ensure owners receive fair returns on investment and creditors and personnel are paid when due.

### 1.3. Relationship with Other Standards

In addition to AS/NZS ISO 9001, Quality Management Systems – Requirements, **Insert Your Company** may use other standards as guidance for its operational and quality management system.

These standards may include but, are not limited to the following:

- AS/NZS ISO 9000, Quality Management Systems - Fundamentals and Vocabulary.
- AS/NZS ISO 9004, Quality Management - Quality Management System - Guidelines to Achieve Sustained Success.
- AS/NZS 10001, Quality management - Customer Satisfaction - Guidelines for Codes of Conduct for Organizations.
- AS/NZS 10002, Quality Management - Customer Satisfaction - Guidelines for Complaints Handling In Organizations.
- ISO 10003, Quality Management - Customer Satisfaction - Guidelines for Dispute Resolution External to Organizations.
- ISO 10004, Quality Management - Customer Satisfaction - Guidelines for Monitoring and Measuring Customer Satisfaction.
- AS ISO 10005, Quality Management - Guidelines for Quality Plans.
- ISO 10006, Quality Management - Guidelines for Quality Management in Projects.
- AS ISO 10007, Quality Management - Guidelines for Configuration Management.
- ISO 10008, Quality Management - Customer Satisfaction - Guidelines For Business-To-Consumer Electronic Commerce Transactions.
- AS/NZS ISO 10012, Measurement Management Systems - Requirements for Measurement Processes and Measuring Equipment.
- AS ISO 10013, Guidelines for Quality Management System Documentation.
- AS/NZS ISO 10014, Quality Management Systems - Guidelines for Realizing Financial Benefits.
- AS/NZS ISO 10015, Guidelines for the Selection of Quality Management System for the Provision of Their Services.
- AS/NZS ISO 14001, Environmental Management Systems - Requirements with Guidelines for Use.
- AS/NZS 19011, Guidelines for Auditing Management Systems.
- AS/NZS 31000, Risk Management – Guidelines.
- ISO 37500, Guidance on Outsourcing.

Delete or add to the above as applicable.

## Terms and Definitions

Term	Definition
<b>Audit</b>	A systematic, independent and documented process for obtaining evidence of conformity to a set of standards and evaluation to determine the extent of compliance.
<b>Audit Evidence</b>	Documentation, statements and records; may also include physical items.
<b>Continual Improvement</b>	A recurring activity to enhance performance.
<b>Corrective Action</b>	An action to eliminate and control the cause of any identified non-conformance to the Quality Management System.
<b>Documented Information</b>	Any document, record or information which is necessary for the operation of the Quality Management System. It can include plans, diagrams, videos, process procedures and so on on any medium, i.e. paper or electronic.
<b>Inputs</b>	Resources such as personnel, equipment, information or finance that are put into a system to produce a desired output.
<b>Inspection and Test Report</b>	A documented systematic approach to inspecting and testing a product, service or process.
<b>Interested Parties</b>	Stakeholders who have an interest in the products and services, or who may be affected by them, or those parties who may otherwise have a significant interest in (or to) <b>Insert Your Company</b> .
<b>Manufacturer's Statement and Report (MDR)</b>	A document outlining the process involved in manufacturing a medical device.
<b>National Association of Testing Authorities (NATA)</b>	Australia's national accreditation body for the accreditation of laboratories, inspection bodies, calibration services, product and certified reference materials and proficiency testing service providers throughout Australia.
<b>Non-Conformance</b>	Non-fulfilment of a requirement.
<b>Non-Conformance Report</b>	A report that documents the details of a non-conformance identified in an audit or other process review.
<b>Objectives</b>	The result to be achieved. <b>Insert Your Company</b> objectives must be S-M-A-R-T: Specific, Measurable, Achievable, Realistic and Timely.
<b>Opposition</b>	A positive effect of uncertainty.
<b>Organizational Knowledge</b>	Knowledge specific to <b>Insert Your Company</b> . It is generally gained by experience and is information that is used and shared for the benefit of objectives.
<b>Outputs</b>	The result of a process.

Term	Definition
<b>Plan-Do-Check-Act</b>	A system to ensure that all actions are planned and checked before the action takes place.
<b>Procedure</b>	A specified way to carry out an activity or process.
<b>Process</b>	A set of interrelated or interacting activities which uses inputs to deliver outputs. Processes are how <b>Insert Your Company</b> typically operates on a daily basis.
<b>Products and Services</b>	The outputs that <b>Insert Your Company</b> delivers to meet the customer's requirements. A product is a physical item or a process while a service is the movement or action that meets the customer's requirements.
<b>Quality Assurance</b>	A part of quality management that is based on providing confidence that quality requirements are fulfilled.
<b>Quality Control</b>	Operational techniques and activities which are used to sustain the quality of products or services, and to ensure that these techniques and activities are given necessary resources.
<b>Record</b>	Document(s) stating the achievement or performance of activities performed.
<b>Risk</b>	The likelihood of negative events.
<b>Risk Assessment</b>	The overall process of identifying, analysing and risk evaluation.
<b>Risk Based Thinking</b>	Planning <b>Insert Your Company</b> activities and actions with consideration of known risks and their potential effects. The identification is to assess the likelihood or impact of unwanted outcomes.
<b>Risk Mitigation</b>	Any development with the intent of addressing all known or suspected risks and preventing their occurrence.
<b>Stakeholder</b>	A person or group of people that has an interest in or is impacted by <b>Insert Your Company</b> policies or activities. Stakeholders may participate in and contribute to the decision making process. Stakeholder may be used interchangeably with 'interested party'.
<b>Supplier</b>	Entity engaged by the <b>Insert Your Company</b> to supply products, services, plant, equipment, materials or other items.
<b>Target</b>	The specific performance requirements that need to be met to achieve objectives.
<b>Uncertainty</b>	A deficiency of information related to understanding or knowledge of an event, its consequence, or likelihood. (Not to be confused with measurement uncertainty.)
<b>Uncontrolled Document</b>	An informal copy of a document for which no attempt is made to update it after distribution.

Term	Definition
<b>Worker</b>	An employee, a contractor or sub-contractor, an employee of a contractor or sub-contractor, an employee of a labour-hire company who has been assigned to work, an apprentice or trainee or a student gaining work experience. May also be referred to as 'personnel'.

For further clarification on terms and definitions, please refer to AS/NZS ISO 9000, Quality Management Systems - Fundamentals and Vocabulary.

## 2. PURPOSE

The purpose of this manual is to describe **Insert Your Company** quality management system, define accountabilities and to provide procedures that will ensure that we do not impact the quality of our processes, products and services.

This manual was developed to guide **Insert Your Company** activities and to provide external parties (upon request) with information regarding our quality management system.

## 3. QUALITY MANAGEMENT MANUAL INSTRUMENTATION

This quality management manual is intended to be used by the employees, contractors and other agents working for, or on behalf of **Insert Your Company** and relies upon their consultation, cooperation and compliance with its full implementation to be feasible throughout the operational life of the company. **Insert Your Company** shall ensure that its employees, contractors and agents for compliance with the quality management system are reviewed at regular intervals, based on the risk of operational non-compliance.

## 4. CONTEXT OF THE ORGANIZATION

### 1. Understanding the Organization and its Context

**Insert Your Company** is committed to defining our position in the marketplace and understanding the internal and external factors arising from internal and external issues influence our ability to achieve our purpose and the ability of our quality management system to deliver the intended outcomes.

Understanding the organizational context requires an analysis of the internal and external issues (refer to the table below), and the risks and opportunities that (may be) of concern to **Insert Your Company** and our interested parties. The results of this analysis are identified in the Q-MF-01 - Organizational Context Register.

**Insert Your Company** then monitors and reviews this information to ensure that a recurrent understanding of each (internal and external) group's requirements is maintained.

Additionally, to further facilitate the understanding of our context, **Insert Your Company** regularly considers internal and external issues that influence our



organizational context during management review meetings. Outcomes are then conveyed via meeting minutes and business planning documents.

#### A Summary of Internal and External Parties and Issues

Internal	External
Workers.	Customers and suppliers.
Market share.	Markets and competition.
Physical resources.	Regulatory and statutory.
Performance.	Technological.
Values and culture.	Cultural and social.
Innovation and knowledge.	General public.

#### 4.2. Understanding the Needs and Expectations of Interested Parties

Interested party management is critical to the success of **Insert Your Company**, as such, we shall take actions to actively understand and manage the positive and negative and changing influences from a range of interested parties.

**Insert Your Company** shall ensure that our people and management team are aware of the context in which our company operates within the business framework. To do this we will consider our aspects of business in a broader context, examine the internal and external needs and expectations of interested parties and determine the most important processes to ensure our quality management systems apply.

**Insert Your Company** will ensure effective interested party management by considering:

- The quality management policy and its implementation.
- Our quality management system objectives and targets.
- The effectiveness of quality management ensure that our products and services continually meet or exceed the needs and expectations of internal and external parties.
- The consequences and actions (if any) of non-conformances within our responsibilities against internal and external parties' requirements, needs and expectations.

##### 4.2.1. Interested Parties

**Insert Your Company** recognizes that we have a unique set of interested parties whose needs and expectations change and develop over time; such needs and expectations include those shown in the table below.

Interested Parties	Needs and Expectations
Workers including contractors and visitors	Shared safety values and security
Customers.	Price, reliability and value.
Distributors and retailers.	Ethics, quality, price and logistics.
Owners/shareholders.	Profitability and growth.

Interested Parties	Needs and Expectations
Suppliers.	Ethics, beneficial relationships.
Regulatory and statutory bodies.	Compliance and reporting.
Workers' organizations (Unions)	Compliance ethics and values

To ensure that our products, services and processes meet all requirements, we proactively identify and assess potential impacts and risks that may otherwise be prompted from an interested party. We then adapt any new need or expectation into our quality management system and continual improvement process.

Needs and expectations of interested parties shall be listed in the Q-MF-0 - Organizational Context Register - Interested Parties Register. This information shall be used by management to assist with the company's strategic direction. Refer to Q-MF-0 and Q-MF-0 - Strategic Objectives and Direction.

#### 4.2.2. Our Strategic Objectives and Direction

**Insert Your Company** strategic objectives and direction are driven by internal and external factors. Accordingly, senior management shall evaluate, plan, monitor these external and internal factors to develop strategies to improve business processes and performance.

Senior management understand that issues and opportunities that the company can leverage from a risk which the company requires plans to mitigate these risks to an acceptable level.

To understand the internal factors, the management shall monitor and consider issues coming from:

- The company's values
- The company's culture and ways of operating
- Intellectual property
- The ongoing relevance of the company against our plans, objectives and targets.

To understand the external factors, the management team will monitor and consider issues coming from:

- Legal and legislative requirements.
- Technological changes.
- Market conditions.

and the economic environment in which we operate.

#### Documents

ID	Documents and Documents
Q-MF-0	Strategic Objectives and Direction
Q-MF-1	Organizational Context Register
Q-MF-3	Quality Management Review Meeting Record

#### 4.3. Scope of the Quality Management System

**Insert Your Company** has established the scope of our quality management system based on the analysis of the issues and requirements discussed in sections 4.1 and 4.2 and assessed using Q-MF-01 – *Organizational Context Register*.

The quality management manual applies to the products and services offered by **Insert Your Company**, inclusive of:

- Add as applicable.

Where any process, product or service is outsourced, **Insert Your Company** shall determine the criteria and methods of control to ensure conformity to customer and regulatory requirements.

In effect, the application of our quality management system shall:

- Demonstrate our ability to consistently provide a high level of customer service through the compliance of applicable regulatory requirements.
- Provide customer satisfaction by continuing to meet best practice levels through a commitment to the effective application of quality management.
- Create a foundation for the achievement of **Insert Your Company** and the continual improvement of our service.

The scope of our quality management system has been assessed against the conformance requirements of *AS/NZS ISO 9001, Quality Management System - Requirements*, utilizing an internal review and assessment methodology.

#### 4.3.1. Exclusions

The following table identifies exclusions from *AS/NZS ISO 9001, Quality Management System - Requirements* that are not applicable to our organization, as well as providing a brief narrative to justify the exclusion from the scope of our quality management system.

ISO 9001 Clause	Justification for Exclusion
8.3	We have not designed or developed any products from our QMS as we do not design or manufacture products.
	Will need to be mitigated by: <b>Insert Your Company</b> X will not design or develop the equipment or service used in the calibration of the equipment that is calibrated. The equipment used in the calibration is based on published and verifiable performance specifications provided by the equipment manufacturer and/or the customer. Clause 7.3 of the <i>AS/NZS ISO 9001, Quality Management System - Requirements</i> standard is not applicable.
	Will need to be mitigated: e.g. <i>AS/NZS ISO 9001, Quality Management System - Requirements</i> clause 7.4 Purchasing.

#### 4.4. Quality Management System and its Processes

**Insert Your Company** quality management system follows the layout and structure of *AS/NZS ISO 9001, Quality Management Systems - Requirements*, and its processes are designed around the principles of the **Plan-Do-Check-Act** methodology, as outlined below.

<b>PLAN</b>	Establish plans, objectives, targets and processes necessary to deliver the required output conforming to the customer's requirements and the organization's policies.
<b>DO</b>	Implement the processes required to convert the inputs into the outputs, as planned.
<b>CHECK</b>	Monitor and measure processes, plans, objectives and targets against the policies, objectives and requirements and report on the results.
<b>ACT</b>	Develop corrective and preventative actions to improve the processes, so that the conversion of inputs to outputs is effective and efficient.

The quality management system is designed as an interrelated number of processes. The main processes of the system are grouped into the categories shown below, with further process details provided in the **Plan-Do-Check-Act** Manual.

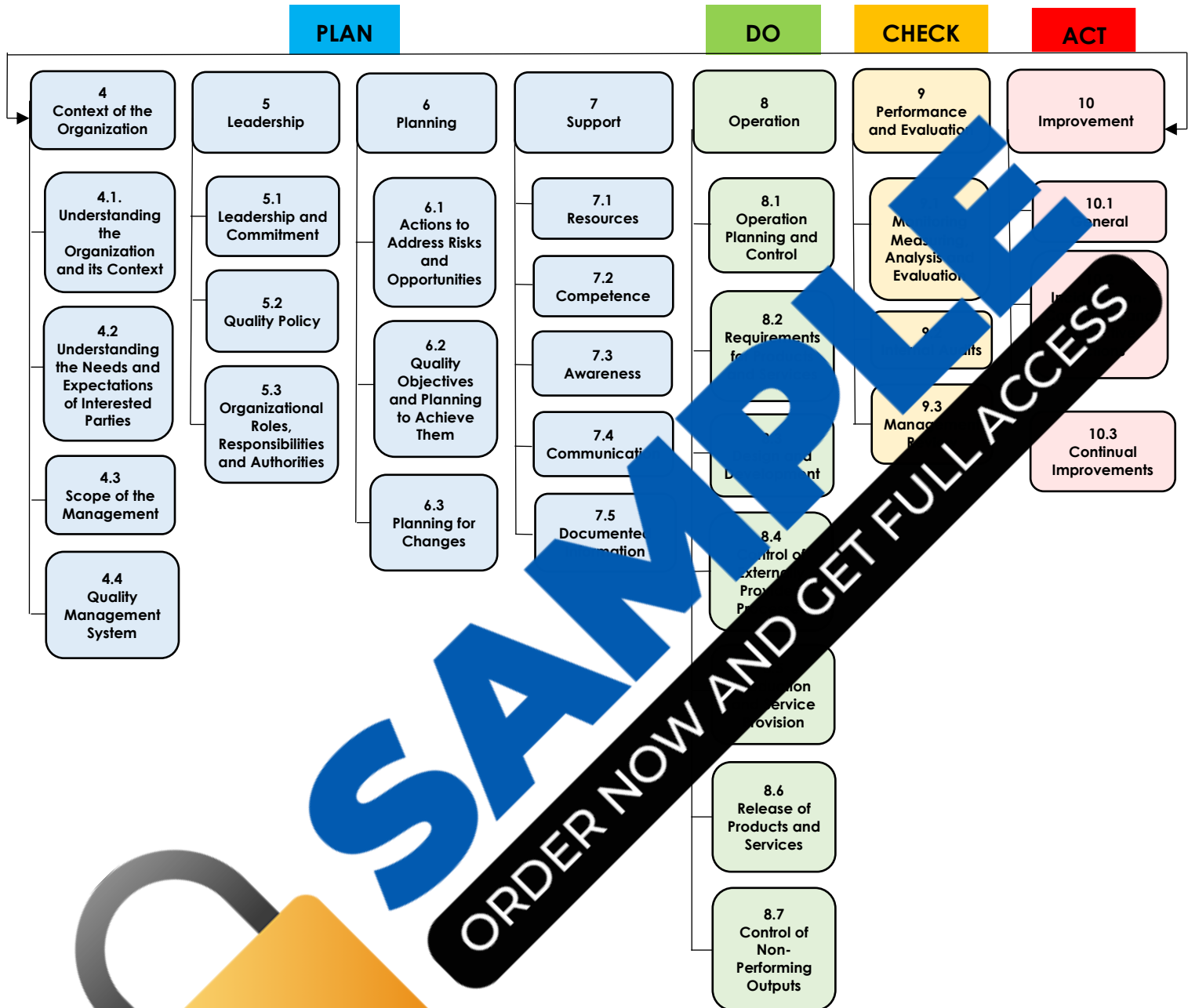
- Leadership Processes.
- Planning Processes.
- Support Processes.
- Operational Processes.
- Performance Evaluation Processes.
- Improvement Processes.

Underpinning these processes is a robust control system, including this quality management manual, policies, forms, other internal and external documents and data needed to manage, perform or monitor product and service quality. Refer to section 1.2 **Sequence of Procession Processes** which shows the sequence and location of the main groups within our quality management system.





## Plan-Do-Check-Act Flowchart



The process and its subsequent output is measured and monitored through internal audits, quality inspections and data analysis.

Performance indicators that are linked to our objectives and other desired outputs are used to measure and monitor progress. **Insert Your Company** also undertakes assessments to determine the risks and opportunities that may be inherent to each.

Current strategies for objectives and other desired outputs is recorded in Q-MF-1 – *Organizational Context Register*, Q-MF-0 – *Strategic Objectives and Direction*, Q-MF-17 *Objectives and Targets Register* and management review meeting records.

### Related Forms and Documents

ID	Forms and Documents
Q-MF-0	Strategic Objectives and Direction