

Quality management input comprises the standard requirements from ISO 9001:2015 which are deployed by our organization to achieve customer satisfaction through process control.

# Quality Manual

ISO 9001:2015 Quality  
Management System





## Table of Contents

<b>1</b>	<b>INTRODUCTION .....</b>	<b>4</b>
<b>2</b>	<b>REFERENCES.....</b>	<b>5</b>
<b>3</b>	<b>DEFINITIONS.....</b>	<b>5</b>
<b>4</b>	<b>ABOUT OUR ORGANIZATION.....</b>	<b>6</b>
4.1	ORGANIZATIONAL CONTEXT.....	6
4.2	RELEVANT INTERESTED PARTIES.....	7
4.3	QUALITY MANAGEMENT SYSTEM SCOPE .....	7
4.4	QUALITY MANAGEMENT SYSTEM PROCESSES .....	8
<b>5</b>	<b>LEADERSHIP &amp; GOVERNANCE.....</b>	<b>10</b>
5.1	LEADERSHIP AND COMMITMENT .....	10
5.1.1	General.....	10
5.1.2	Customer Focus.....	11
5.2	QUALITY POLICY .....	11
5.2.1	Establishing the Quality Policy .....	11
5.2.2	Communicating the Quality Policy.....	12
5.2.3	Quality Policy Statement .....	12
5.3	ROLE, RESPONSIBILITIES AND AUTHORITIES.....	13
5.3.1	Top Management.....	13
5.3.2	Quality Manager .....	13
5.3.3	Department Managers .....	14
5.3.4	Employees .....	14
<b>6</b>	<b>MANAGEMENT SYSTEM PLANNING .....</b>	<b>15</b>
6.1	ADDRESSING RISKS & OPPORTUNITIES.....	15
6.2	QUALITY OBJECTIVES .....	16
6.3	PLANNING FOR CHANGE .....	17
<b>7</b>	<b>SUPPORT .....</b>	<b>19</b>
7.1	RESOURCES .....	19
7.1.1	General.....	19
7.1.2	People .....	19
7.1.3	Infrastructure.....	19
7.1.4	Operational Environment.....	20
7.1.5	Monitoring & Measurement Tools.....	20
7.1.6	Organizational Knowledge .....	21
7.2	COMPETENCE.....	22
7.3	AWARENESS.....	22
7.4	COMMUNICATION.....	23
7.4.1	General.....	23
7.4.2	Internal Communication.....	23
7.4.3	External Communication .....	23
7.5	DOCUMENTED INFORMATION .....	24
7.5.1	Management System Documents.....	24
7.5.2	Creating & Updating.....	24
7.5.3	Controlling Documented Information.....	25

<b>8</b>	<b>OPERATION.....</b>	<b>26</b>
8.1	OPERATIONAL PLANNING & CONTROL .....	26
8.2	CUSTOMER REQUIREMENTS .....	26
8.2.1	Customer Communication.....	26
8.2.2	Determining Requirements .....	27
8.2.3	Review of Requirements.....	27
8.2.4	Changes in Requirements .....	27
8.3	DESIGN & DEVELOPMENT.....	27
8.3.1	General.....	27
8.3.2	Planning.....	28
8.3.3	Inputs.....	28
8.3.4	Controls .....	29
8.3.5	Outputs.....	29
8.3.6	Changes.....	30
8.4	CONTROL OF SUPPLIERS & EXTERNAL PROCESSES .....	30
8.4.1	General.....	30
8.4.2	Purchasing Controls .....	31
8.4.3	Purchasing Information.....	31
8.5	PRODUCTION & SERVICE PROVISION.....	32
8.5.1	Control of Production & Service Provision .....	32
8.5.2	Identification & Traceability .....	32
8.5.3	3 <sup>rd</sup> Party Property.....	33
8.5.4	Preservation .....	33
8.5.5	Post-delivery Activities .....	34
8.5.6	Control of Changes.....	34
8.6	RELEASE OF PRODUCTS & SERVICES.....	34
8.7	CONTROL OF NON-CONFORMING OUTPUTS.....	35
<b>9</b>	<b>PERFORMANCE EVALUATION .....</b>	<b>36</b>
9.1	MONITORING, MEASUREMENT, ANALYSIS & EVALUATION.....	36
9.1.1	General.....	36
9.1.2	Customer Satisfaction.....	36
9.1.3	Analysis and Evaluation.....	37
9.2	INTERNAL AUDIT.....	37
9.3	MANAGEMENT REVIEW .....	38
9.3.1	General.....	38
9.3.2	Inputs.....	39
9.3.3	Outputs.....	39
<b>10</b>	<b>IMPROVEMENT.....</b>	<b>40</b>
10.1	GENERAL.....	40
10.2	NON-CONFORMITY & CORRECTIVE ACTION .....	40
10.3	IMPROVEMENT .....	41
	<b>APPENDICES.....</b>	<b>42</b>
A.1	CORRELATION MATRIX.....	42
A.2	SEQUENCE & INTERACTION OF QMS PROCESSES.....	44
A.3	ORGANIZATION CHART .....	45

# 1 Introduction

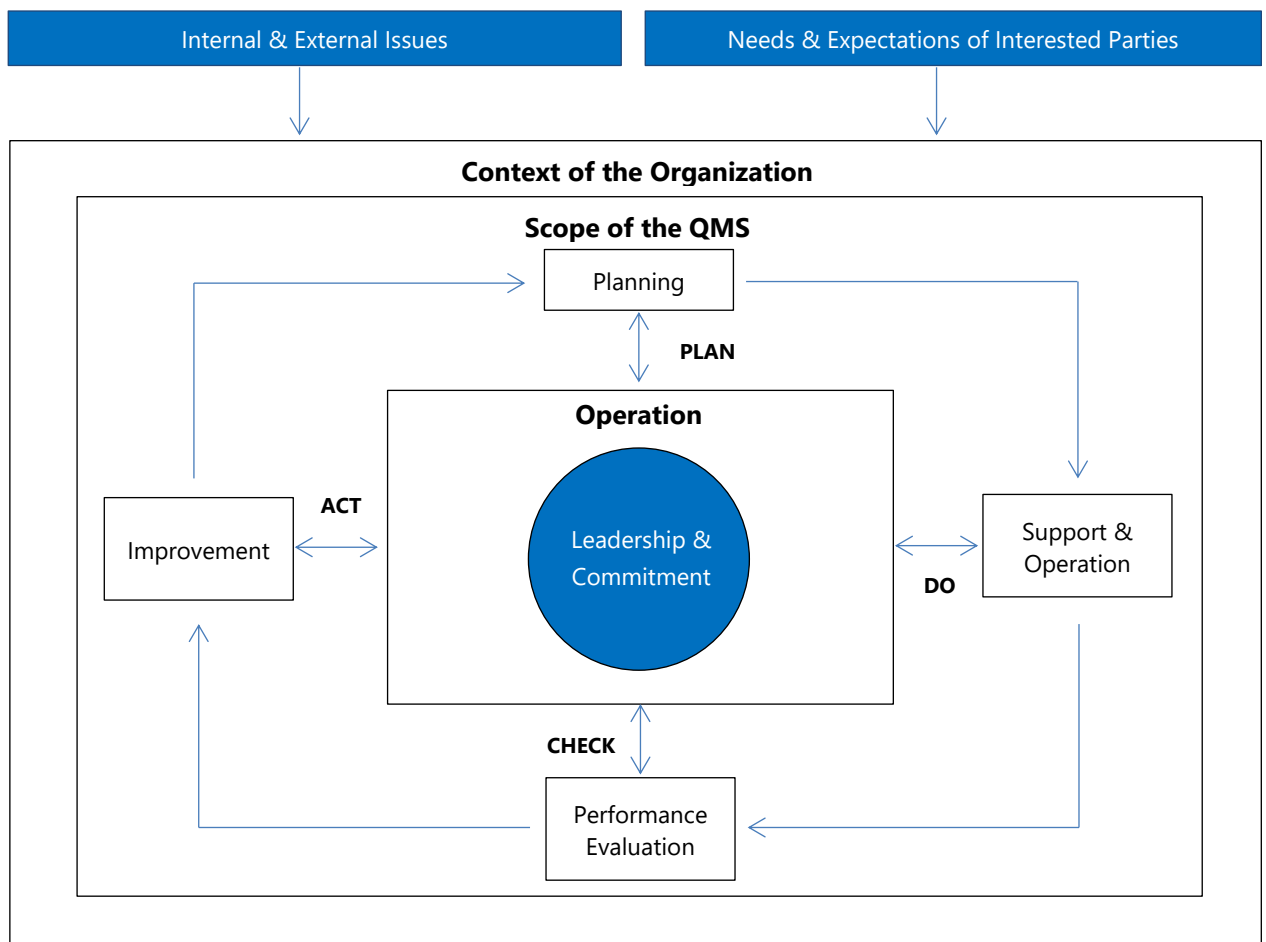
Your organization has developed and implemented a quality management system (QMS), which uses ISO 9001:2015 as framework that allows our organization to document and improve our practices in order to better satisfy the needs and expectations of our customers, stakeholders and interested parties.

This QMS manual is used to familiarise our customers, interested parties, or individuals with the controls that have been implemented and to assure them that the integrity of our QMS is maintained and is focused on meeting its intended outcomes.

This manual also describes the structure and interactions of our QMS, delineates authorities, inter relationships and responsibilities of personnel who operate within the boundaries of your organization's Quality Management System. The manual also references procedures, process and activities that comprise our QMS.

The Figure below illustrates our methodology for the development of our QMS, using the plan, do, check and act process approach, to implement and deliver management system objectives, stakeholder requirements and customer satisfaction.

**Figure 1: ISO 9001:2015 QMS & PDCA Interaction**



Certification to the international standard ISO 9001:2015 will help achieve these intended outcomes and demonstrates that the QMS is effective, provides value for our organization and its interested parties. Our

## 4 About Our Organization

### 4.1 Organizational Context

Your organization is committed to defining our position in the marketplace and understanding how relevant factors arising from legal, political, economic, social and technological issues influence our strategic direction and our organizational context.

Your organization identifies, analyzes, monitors and reviews factors that may affect our ability to satisfy our customers and stakeholders, as well as; factors that may adversely affect the stability of our process, or our management system’s integrity.

To ensure that our QMS is aligned with our strategy, whilst taking account of relevant internal and external factors; we initially collate and analyze pertinent information in

order to determine potential impact on our context and subsequent business strategy. Such issues include factors that are capable of being affected by, or capable of affecting our organization. Broadly, these issues are defined as:

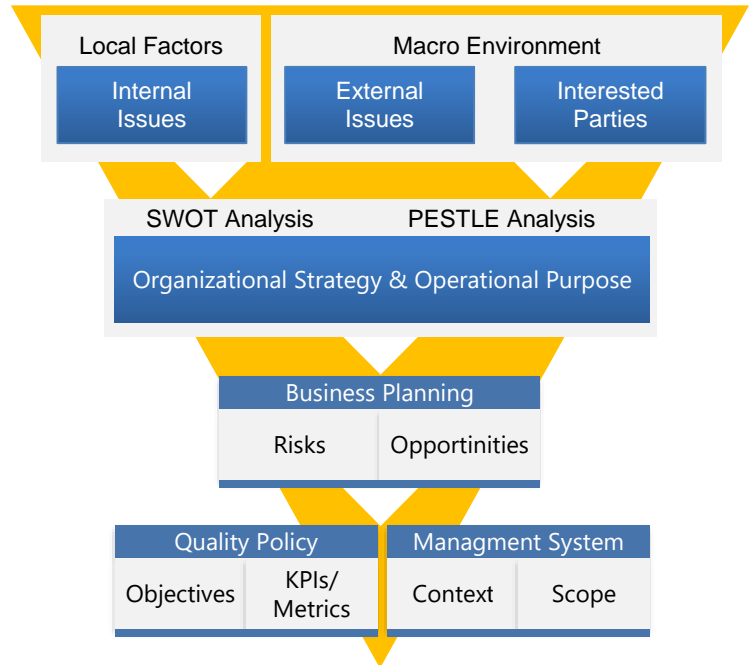
1. **Internal issues** – conditions related to our organizational activities, products, services, strategic direction, culture, people, knowledge, processes and systems. Using *SWOT analysis* provides our organization with framework for reviewing and evaluating our strategies, and the position and direction of our organization, business propositions and other ideas;
2. **External issues** – conditions related to cultural, social, political, legal, regulatory, financial, technological, economic, competition at local, national or international levels. Using *PESTLE analysis* provides our organization with framework for measuring our market and growth potential according to external political, economic, social, technological, legal and environmental factors.

Your organization then monitors and reviews this information to ensure that a continual understanding of each group’s requirements is derived and maintained. To facilitate the understanding of our context, we regularly consider issues that influence our context during management review meetings using the *Context & Strategy Analysis* template. The results of which are conveyed via minutes and business planning documents.

Although we acknowledge that ISO 9001:2015 does not require our organizational context to be maintained as documented information, we maintain and retain; in addition to this document, the following documented information to describe our organizational context:

1. *Context & Strategy Analysis* underpins our **policies** and provides a road map to achieve **future goals**;
2. *SWOT Analysis* to help understand **internal issues**;
3. *PESTLE Analysis* to help understand **external issues**;

Figure 2: QMS Strategy Input Hierarchy



4. Analysis of business plans, strategies, and statutory and regulatory commitments;
5. Analysis of technology and competitors;
6. Economic reports from relevant business sectors;
7. Technical reports from technical experts and consultants;
8. Minutes of meetings (Management and design review minutes), process maps and reports, etc.

The outputs from these activities are evident as an input to determining the scope of our QMS (Refer to Section 4.3) and its processes (Refer to Section 4.4), as well as, the consideration of risks and opportunities that may affect our QMS, and the resulting actions that we take to address them (Refer to Section 6.1).

SWOT analysis provides our organization with framework for reviewing and evaluating our strategies, and the position and direction of our organization, business propositions and other ideas. Similarly PESTLE analysis provides our organization with framework for measuring our market and growth potential according to external political, economic, social, technological, legal and environmental factors.

## 4.2 Relevant Interested Parties

Your organization recognizes that we have a unique set of interested parties whose needs and expectations change and develop over time, and furthermore; that only a limited set of their respective needs and expectations are applicable to our operational purpose. Such needs and expectations broadly include those shown in the table below.

Interested Parties	Needs & Expectations
Customers	Price, reliability & value
Distributors & retailers	Quality, price & logistics
Owners/shareholders	Profitability & growth
Employees	Shared values & security
Suppliers	Beneficial relationships
Regulatory & statutory	Compliance & reporting

To ensure that our products and processes continue to meet all relevant requirements, we identify and assess the potential impact of any relevant needs and expectations that may be elicited from interested parties.

The results of the assessment are captured using the *Interested Party Analysis* template.

Where appropriate, to ensure that our processes are aligned to deliver the requirements of our interested parties; we convert relevant needs and expectations into requirements which become inputs to our QMS and to our product and service designs.

## 4.3 Quality Management System Scope

Based on the scope of our activities described in Section 1 - Introduction and the analysis of the issues and requirements identified in Sections 4.1 and 4.2, your organization has established the scope of our quality management system in order to implement our objectives and our policies that are relevant to our context, products and any interested parties.

In order for our QMS to be robust, all the activities, products and services undertaken by your organization are included within the scope of the QMS. In this way, we are able to control and influence our activities, products and services.

This document describes our quality management system, delineates authorities, inter-relationships and responsibilities of process owners and personnel that operate within the system. Although we recognize that

ISO 9001:2015 does not require a quality manual, we have decided to retain and update our quality manual, as our employees, customers, suppliers and other stakeholders perceive it to add value to our operations.

This document also demonstrates the relationship between our quality management system and the sequence and interaction of our key processes. Conformance to ISO 9001:2015 has been verified utilizing a formal assessment and review process by <insert name of Registrar>.

### 4.4 Quality Management System Processes

Your organization has implemented a quality management system that exists as part of a larger strategy that has established, documented and implemented our processes, quality policies and objectives, whilst satisfying the requirements of ISO 9001:2015.

To achieve this, your organization has adopted the process approach advocated by ISO 9001:2015. Top management has determined the processes required for achieving the intended outputs. The *Process Clause Matrix* template is used to record and assign requirements to relevant functions, departments, teams, and personnel. By defining key process-groups and by managing their inputs, activities, controls, outputs and interfaces; we ensure that system effectiveness is established and maintained. These key process groups comprise:

1. Management and review processes;
2. Operation and production processes;
3. Support and assurance processes.

These process groups are described using tools such as documented procedures, process maps, flow diagrams, matrices, schedules, and charts, etc. Refer to *Appendix A.2* which shows the sequence and interaction of the process groups within our management system.

It is recognized that defining, implementing and documenting our quality management system is only the first step towards fully implementing its requirements. The effectiveness of the each process and its subsequent output is measured and evaluated through regular internal audits, quality inspections and data analysis.

The monitoring of key performance indicators (KPIs), which are linked to our objectives, is used to measure and communicate process performance. This approach allows Top management to regularly review the QMS to ensure its ongoing integration with in the business.

As part of the decision making process, we use trends and statistical data related to non-conformities, quality related aspects, targets, objectives and corrective actions, as well as, monitoring and measurement results, audit results and compliance data, to ensure that objective, and responsible management decisions are made.

**Figure 3 : Key Process Groups**

