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

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 improvement our practices in order to better satisfy the needs and expectations of our customers, stakeholders and interested parties.

This manual describes the quality management system, delineates authorities, inter relationships and responsibilities of personnel responsible for performing within the system. The manual also provides references to procedures and activities that comprise our quality management system.

The manual is used to familiarise customers and other external organizations or individuals with the controls that have been implemented and to assure them that the integrity of our quality management system is maintained and is focused on customer satisfaction and continual improvement.

Our quality management system meets the requirements of ISO 9001:2015 and uses the Plan, Do, Check and Act approach to process planning. Our QMS addresses and supports our strategies for the <design, development, manufacturing, installation and servicing of our products>. <insert your scope statement here. This should succinctly summarize your products and/or services. A single sentence is all that is required, as this will be shown your ISO 9001:2015 certificate>.

<Also insert the registered address of your organization here>

The following table identifies any ISO 9001:2015 requirements, from Section 8.0, that are not applicable to our organization as well as providing a brief narrative to justify their omission from the scope of our QMS:

Clause	Justification for Exclusion
8.3	We exclude design and development from our QMS, as we do not design or modify components

2 References

In addition to ISO 9001:2015 we also make reference to other relevant British and/or international standards as well as customer specifications appropriate to our products and market.

Standard	Title	Description
BS EN ISO 9000:2015	Quality management systems	Fundamentals and vocabulary
BS EN ISO 9004:2000	Quality management systems	Guidelines for performance improvements
BS EN ISO 19011:2011	Auditing management systems	Guidelines for auditing

3 Definitions

This document does not introduce any new definitions but rather relies on the following:

1. Definitions typically used by our customers, stakeholders or marketplace;
2. Terms typically used in standards and regulations as they relate to our QMS or products;
3. Standard business terminology;
4. Terms and vocabulary commonly used in quality and <engineering> practices.

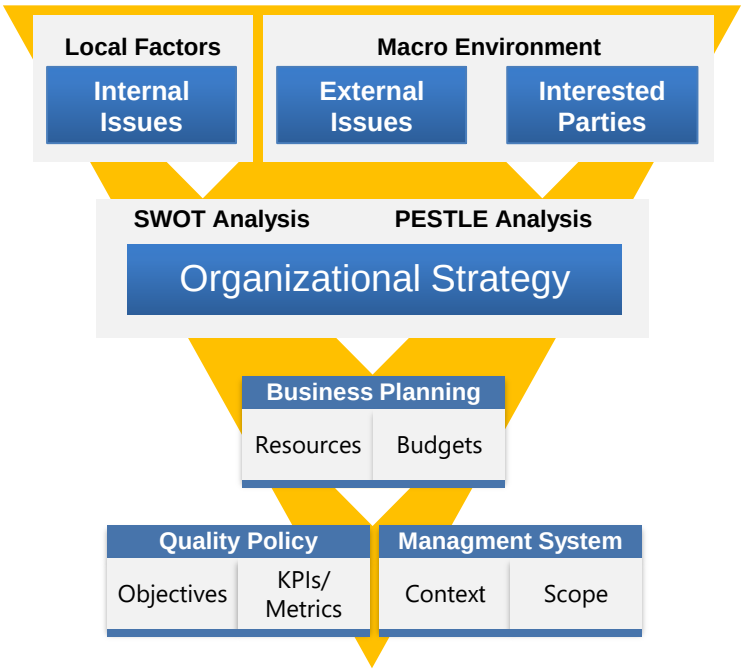
4 About Our Organisation

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.

Figure 1: Typical QMS Input Hierarchy



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.

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 Plan* template. The results of which are conveyed via minutes and business planning documents.

Internal Issues	External Issues
Market share	Customers & suppliers
Employees	Markets & competition
Performance	Regulatory & statutory
Capacity	Economic backdrop
Values & culture	Technological
Innovation & knowledge	Cultural & social

The output from this activity is evident as an input to the consideration of risks and opportunities, and the actions that we take to address them. Refer to Section 6.1 for more information about our risk and opportunity management framework.

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. Analysis of business plans, strategies, and statutory and regulatory commitments;
2. Analysis of technology and competitors;
3. Economic reports from relevant business sectors;
4. Technical reports from technical experts and consultants;
5. SWOT analysis reports or schedules for internal issues;
6. PESTLE analysis reports or schedules for external issues;
7. Minutes of meetings (Management and design review minutes), process maps and reports, etc.

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 operations or to our QMS. 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 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

4.3.1 Management System Scope

Based on 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 the implement our objectives and our policies that are relevant to our context, products and any interested parties.

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>.

4.3.2 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 and personnel.

By defining four key process-groups and by managing their inputs, activities, controls, outputs and interfaces; we ensure that system effectiveness is established maintained. These key process groups include:

1. Leadership and planning processes;
2. Customer and stakeholder processes;
3. Product/service development processes;
4. Evaluation and improvement processes.

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

Figure 2 : Key Process Groups

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.

We use key performance indicators (KPIs) that are linked to our objectives to control and monitor our processes, as well as assessments to determine the risks and opportunities inherent to each process. We use trends and indicators relating to non-conformities, objectives and corrective action, as well as, monitoring and measurement results, audit results and customer satisfaction data, process performance and the conformity of our products.

4.3.3 Outsourced Processes

Where your organization identifies the requirement to outsource any process, or part thereof, which affects conformity with the stated requirements; your organization identifies control criteria such as; the competence of personnel, inspection regimes, the provision of product conformity certificates, adherence to specifications and specific job files, etc. Refer to Section 8.4.

The controls identified do not absolve us of the responsibility to conform to client, statutory and regulatory requirements but instead they enhance our capacity to effectively manage our supply chain. The controls adopted are influenced by the potential impact of outsourcing on meeting customer or stakeholder requirements, and the degree to which control of the process is shared. Outsourced processes are controlled via purchasing and contractual agreements. Refer to Section 8.4.

4.3.4 Documented Information

4.3.4.1 Management System Documents

Your organization ensures that our QMS includes the documented information that is required to be maintained and retained by ISO 9001:2015, and additionally, any documented information identified by our

organization that demonstrates the effective operation of our QMS. Refer to the *Master Document & Record Index*.

Your organization applies the following criteria to all types of documented information in order to assess whether the information is necessary for demonstrating the effectiveness of our QMS, and whether it should be formally controlled. Should any of the criteria apply, your organization ensures that this information is retained and/or maintained as a form of 'documented information'.

1. Communicates a message internally or externally;
2. Provides evidence of process and product conformity;
3. Provides evidence that planned outputs were achieved;
4. Provides knowledge sharing.

Should any of the above criteria apply, your organization ensures that this information is retained and/or maintained as a form of 'documented information'

4.3.4.2 Creating & Updating

Your organization ensures that when we create documented information it is appropriately identified and described (e.g. title, date, author, reference number) and is available in an appropriate format (e.g. language, software version, graphics, etc.) and on appropriate media (e.g. paper, electronic). All documented information is reviewed and approved for suitability and adequacy. Where permanent changes to a document are required, a *Document Change Request* form is completed and submitted for the document owner to consideration and implementation.

4.3.4.3 Controlling Documented Information

Documented information is retained to provide evidence of conformity to the requirements specified by ISO standards, customer requirements and of the effective operation of our integrated management system. We use *Document Issue Sheets* to record the transmittal of documents to external parties.

Your organization uses standard forms and templates that are accessed via a local area network computer system. An electronic document management system, which is backed up and updated as required, is used to retain documented information ensuring only the current versions are available to users. All management system documents are controlled and communicated according to the *Control of Documented Information* procedure which defines the process for:

1. Approving documents for adequacy prior to issue;
2. Reviewing and revising as necessary and re-approving documents;
3. Ensuring that changes and current revision status of documents are identified;
4. Ensuring that relevant versions of applicable documents are available at points of use;
5. Ensuring that documents remain legible and readily identifiable;
6. Ensuring that documents of external origin are identified and their distribution controlled;
7. Preventing the unintended use of obsolete documents;
8. Ensuring that documents of external origin are identified and their distribution controlled.

Supporting documentation:

Ref.	Title & Description
01	Documented Information Procedure

Appendices

A.1 Correlation Matrix

This section provides a matrix to correlate the requirements of ISO 9001:2015 against the relevant sections in this document and should be used to determine where the new and amended clauses are located.

ISO 9001:2015		This Document	
4.0	Context of the Organization	4.0	About our Organization
4.1	Understanding the Organization and its Context	4.1	Organizational Context
4.2	Needs and Expectations of Interested Parties	4.2	Relevant Interested Parties
4.3	Scope of the Quality Management System	4.3.1	Management System Scope
4.4	Quality Management System and its Processes	4.3.2	Management System Processes
5.0	Leadership	5.0	Leadership & Governance
5.1	Leadership and Commitment	5.1	Leadership and Commitment
5.1.1	Quality Management System	5.1.1	Quality Management System
5.1.2	Customer Focus	5.1.2	Customer Focus
5.2	Quality Policy	5.1.3	Quality Policy
5.2.1	Establishing the Quality Policy	5.1.3.1	Establishing the Quality Policy
5.2.2	Communicating the Quality Policy	5.1.3.2	Communicating the Quality Policy
5.3	Roles, Responsibilities and Authorities	5.2	Roles, Responsibilities and Authorities
6.0	Planning for the Quality Management System	6.0	Management System Planning
6.1	Actions To Address Risks and Opportunities	6.1	Addressing Risk & Opportunities
6.2	Quality Objectives & Planning To Achieve Them	6.2	Quality Objectives
6.3	Planning of Changes	6.3	Planning for Change
7.0	Support	7	Support
7.1	Resources	7.1	Resources
7.1.1	General	7.1.1	General
7.1.2	People	7.1.2	People
7.1.3	Infrastructure	7.1.3	Infrastructure
7.1.4	Environment for the Operation Of Processes	7.1.4	Operational Environment
7.1.5	Monitoring and Measuring Resources	7.1.5	Monitoring and Measuring Tools
7.1.6	Organizational Knowledge	7.1.6	Organizational Knowledge
7.2	Competence	7.1.2.1	Competence
7.3	Awareness	7.1.2.2	Awareness
7.4	Communication	5.3	Communication
7.5	Documented Information	4.3.4	Documented Information
7.5.1	General	4.3.4.1	Management System Documents
7.5.2	Creating and Updating	4.3.4.2	Creating and Updating
7.5.3	Control of Documented Information	4.3.4.3	Controlling Documented Information
8.0	Operation	8.0	Product & Service Development
8.1	Operational Planning and Control	8.1	Operational Planning and Control
8.2	Requirements for Products and Services	8.2	Customer Requirements
8.2.1	Customer Communication	8.2.1	Customer Communication
8.2.2	Determining Requirements Related to Products	8.2.2	Determining Requirements

A.2 Sequence & Interaction of Processes