

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



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## 4 About Our Organisation

### 4.1 Organizational Context

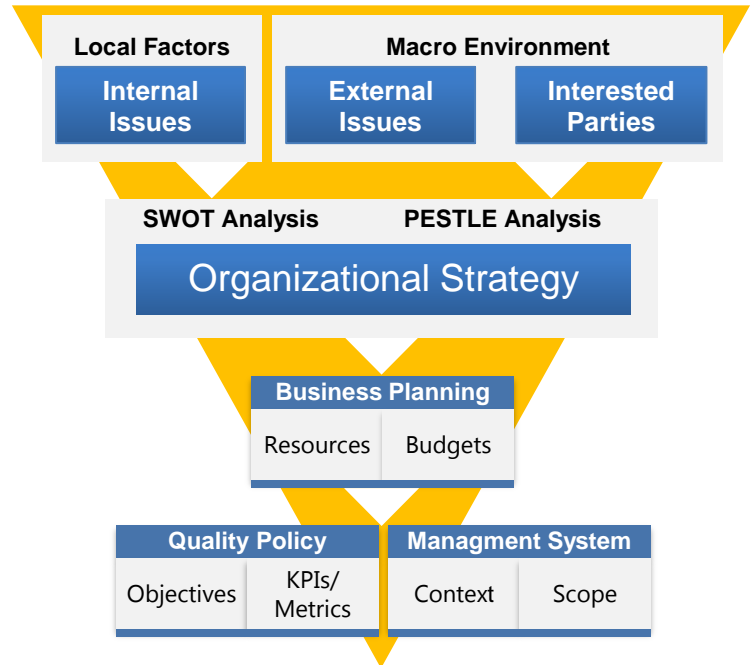
Your organization is committed to defining our position in the marketplace and understanding how relevant factors arising from legal, political, economic, social and technological issues influence our strategic direction and our organizational context.

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.

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 and are conveyed via minutes and business planning documents.

Figure 1: Typical QMS Input Hierarchy



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.

## 5 Leadership & Governance

### 5.1 Leadership and Commitment

#### 5.1.1 Quality Management

Your organization's leadership is also responsible for implementing the QMS, which includes the development and deployment of the quality policy, the quality objectives, and product/project-specific plans that are customer focused.

Top management provides the leadership and governance to all activities related to the lifecycle processes including defining the strategic direction, responsibility, authority, and communication to assure the safe and effective performance.

Your organization's governance structure provides necessary support for creating and establishing appropriate processes that are important for maintaining and achieving our quality objectives and policies.

In addition, governance activities include systematic verification of the effectiveness our QMS by undertaking internal audits and analyzing performance data.

Regular management reviews ensure that our quality management system is adequate and effective, and that any necessary adjustments are made as a result.

Top management is committed to implementing and developing the quality management system and this commitment is defined by our corporate policies and objectives. Your organization ensures that our policies are understood, implemented and maintained throughout at all levels of the organization through printed distribution of our policy statements and through periodic management review of the policy statements and corporate level improvement objectives. Your organization communicates our mission, vision, strategy, policies and processes to all employees in order to:

1. Create and sustain shared values of fairness and ethical behavior;
2. Establish a culture of trust and integrity;
3. Encourage commitment to quality;
4. Provide people with the required resources, training and authority to act with accountability;
5. Inspire, encourage and recognize people's contribution.

Figure 3: Leadership PDCA Cycle



## 6 Management System Planning

### 6.1 Addressing Risks & Opportunities

The overall aim of risk and opportunity management within [your organization](#) is to ensure that organizational capabilities and resources are employed in an efficient and effective manner to take advantage of opportunities and to mitigate risks.

Top management are responsible for incorporating risk based thinking in to our organization's culture. This includes the establishment of risk management policies and targets to ensure effective implementation of risk and opportunity management principles and activities by:

1. Providing sufficient resources to carry out risk and opportunity management activities;
2. Assigning responsibilities and authorities for risk and opportunity management activities;
3. Reviewing information and results from audits and risk and opportunity management activities.

The scope of [your organization's](#) risk and opportunity management process includes the assessment of the internal and external issues identified in Section 4.1, and the assessment of the needs and expectations of any interested parties identified in Section 4.2. Risk and opportunity management is undertaken as part of [your organization's](#) day-to-day operations and is captured at the following hierarchy:

1. Strategic level;
2. Programme level;
3. Department level;
4. Process level;

Establishing such a hierarchy for capturing risk and opportunity ensures that each is managed at the most appropriate level within our organization. Typically, the following categories are assigned to each level in the hierarchy as shown in the table opposite.

Business Hierarchy	Risk/Opportunity
Strategic level	Budgets and profitability
Programme level	Performance and efficiency
Department level	Resources and targets
Process level	Evaluation and assurance

[Your organization](#) has classified its 'risk appetite' as the amount of risk that we are willing to accept in pursuit of an opportunity or the avoidance of risk where each pertains to product and/or system conformity, and which reflect the following considerations:

1. Risk management philosophy per product or process;
2. Capacity to take on or mitigate risk;
3. Our objectives, business plans and respective stakeholder demands;

**Figure 4: Risk & Opportunities PDCA Cycle**



## 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

ISO 9001:2015		This Document	
8.2.3	Review of Requirements Related to the Products	8.2.3	Review of Requirements
8.2.4	Changes to Requirements for Products/Services	8.2.4	Changes in Requirements
8.3	Design and Development of Products	8.3	Design and Development of Products
8.3.1	General	8.3.1	General
8.3.2	Design and Development Planning	8.3.2	Planning
8.3.3	Design and Development Inputs	8.3.3	Inputs
8.3.4	Design and Development Controls	8.3.4	Controls
8.3.5	Design and Development Outputs	8.3.5	Outputs
8.3.6	Design and Development Changes	8.3.6	Changes
8.4	Externally Provided Products & Services	8.4	Control of Suppliers & External Processes
8.4.1	General	8.4.1	General
8.4.2	Type & Extent of Control of External Provision	8.4.2	Purchasing Controls
8.4.3	Information for External Providers	8.4.3	Purchasing Information
8.5	Production and Service Provision	8.5	Production & Service Provision
8.5.1	Control of Production and Service Provision	8.5.1	Control of Production & Service Provision
8.5.2	Identification and Traceability	8.5.2	Identification & Traceability
8.5.3	Customer or External Provider's Property	8.5.3	3 <sup>rd</sup> Party Property
8.5.4	Preservation	8.5.4	Preservation
8.5.5	Post-Delivery Activities	8.5.5	Post-Delivery Activities
8.5.6	Control of Changes	8.5.6	Control of Changes
8.6	Release of Products and Services	8.6	Release of Products and Services
8.7	Non-conforming Process Outputs and Products	8.7	Control of Non-conforming Outputs
9.0	Performance Evaluation	9.0	Performance Evaluation
9.1	Monitoring, Measurement, Analysis & Evaluation	9.1	Monitoring, Measurement, Analysis & Evaluation
9.1.1	General	9.1.1	General
9.1.2	Customer Satisfaction	9.1.2	Customer Satisfaction
9.1.3	Analysis and Evaluation	9.1.3	Analysis and Evaluation
9.2	Internal Audit	9.2	Internal Audit
9.3	Management Review	9.3	Management Review
9.3.1	General	9.3.1	General
9.3.2	Management Review Inputs	9.3.2	Inputs
9.3.3	Management Review Outputs	9.3.3	Outputs
10.0	Improvement	10.0	Improvement
10.1	General	10.1	General
10.2	Non-Conformity and Corrective Action	10.2	Non-Conformity & Corrective Action
10.3	Continual Improvement	10.3	Continual Improvement



### A.2 Sequence & Interaction of Processes

