

Quality Procedure

Context of the Organization

Table of Contents

1	ORGANIZATIONAL CONTEXT	3
1.1	INTRODUCTION & PURPOSE	3
1.1.1	Process Turtle Diagram	3
1.1.2	References	3
1.1.3	Terms & Definitions.....	3
1.2	APPLICATION & SCOPE	4
1.3	UNDERSTANDING ORGANIZATIONAL CONTEXT	4
1.3.1	General.....	4
1.3.2	Capturing & Analyzing Internal Issues.....	4
1.3.2.1	Strengths	5
1.3.2.2	Weaknesses.....	5
1.3.2.3	Opportunities	5
1.3.2.4	Threats.....	5
1.3.3	Capturing & Analyzing External Issues	5
1.3.3.1	Political.....	6
1.3.3.2	Environmental	6
1.3.3.3	Technological	7
1.3.3.4	Social/Cultural	7
1.3.3.5	Legislative	7
1.3.3.6	Economic.....	7
1.3.4	Prioritizing Internal & External Issues.....	7
1.4	NEEDS & EXPECTATIONS OF INTERESTED PARTIES	8
1.4.1	General.....	8
1.4.2	Interested Party Requirements.....	8
1.4.3	Requirement Scoring Matrix	9
1.4.4	Action Matrix.....	9
1.4.5	Monitoring & Review.....	9
1.5	DETERMINING QMS SCOPE.....	10
1.5.1	General.....	10
1.5.2	Determining Scope	10
1.6	APPLYING QMS PROCESSES	11
1.6.1	General.....	11
1.6.2	Mapping Processes.....	11
1.6.3	Process Application	11
1.7	FORMS & RECORDS	11

1.2 Application & Scope

This procedure has been developed to assist in meeting the requirements of Clause 4.0 of ISO 9001:2015. As a prerequisite for risk-based thinking and evidence-based decision making, defining the levels of risk and criteria related to [your organization's](#) internal and external issues, interested party requirements, quality management system scope and its processes. Issues include but are not limited to:

1. Applicable laws;
2. Market and market trends;
3. Competitors including technology;
4. Customers and end users;
5. Policy, objectives, strategies;
6. Promising business opportunities;
7. Personnel qualifications;
8. Management review inputs.

[Your organization's](#) approach to planning the quality management system comprises a set of iterative steps as described below.

1.3 Understanding Organizational Context

1.3.1 General

Knowledge about [our organization's](#) context and the process by which it is obtained is underpinned by tools such as stakeholder mapping to determine importance and levels of engagement and by SWOT and PESTLE analysis.

Only those issues that are relevant to our organization's operational purpose and strategic direction which affect; or have the potential to affect, our ability to achieve our objectives are captured using the [Context & Interested Parties Analysis](#) matrix and considered further.

1.3.2 Capturing & Analyzing Internal Issues

Sources of internal issues may include information relating to the structure of the organization, the identification of roles and responsibilities, and the arrangements for governance; or consultants' reports showing how well the business is performing, and:

1. Statements relating to the organizations mission, vision and core values;
2. Feedback obtained from employees, e.g. employee survey results;
3. Information systems and the mechanism for capturing and sharing knowledge and lessons learned;
4. Organizational capability studies, identification of load or capacity;
5. Resource requirements needed to achieve demand.

The internal context considers the values, culture, knowledge and performance of our organization. Internal issues are initially captured using the [Context & Interested Parties Analysis](#) matrix.

Where required, further understanding of these issues is acquired by SWOT analysis. Using the [SWOT Analysis Template](#) [your organization](#) identifies and analyses our strengths, weaknesses, opportunities and threats, as appropriate:

1.4.3 Scoring Matrix

Each **Departmental Manager** in conjunction with the **Quality Manager** ranks the interested parties according to their degree of Priority and their Relevance (1 low, 4 high) to current objectives, policies and conformity of products and services. The spreadsheet multiplies these scores to generate an overall Power score that represents the Risk Priority Number (RPN) that is used to prioritize the adoption of any relevant need or expectation.

1. **Relevance** – effects upon organizational activities;
2. **Priority** – effects on decisions the organization makes;
3. **Power** – combined effects of influence the interested party has (Risk Priority Number RPN).

Power (<i>Effects of influence</i>) = Priority x Relevance		Priority of Interested Party (<i>Effects on decisions</i>)			
		No importance	Minor importance	Some importance	Major importance
Relevance of Interested Party (<i>Effects on activities</i>)	Not relevant	1	2	3	4
	Minor relevance	2	4	6	8
	Influential	3	6	9	12
	Significantly relevant	4	8	12	16

1.4.4 Action Matrix

Based on the scoring output, each **Departmental Manager** in conjunction with the **Quality Manager** considers, develops and implements the handling approaches, defined in the table below, to manage and comply with the needs and expectations of our interested parties.

Score	Power of Interested Party (<i>Effects on decisions</i>)		
	Description	Strategy	Objectives
1 to 3	Low relevance with low importance	Monitor interest	Detect opportunities from growing interest
4 to 6	Low relevance with high importance	Keep satisfied	Build interest, monitor for changes
7 to 11	High relevance with low importance	Keep informed	Maintain interest, monitor for changes
12 to 16	High relevance with high importance	Manage closely	Maintain support, monitor for changes

The Context & Interested Parties Analysis matrix is submitted to **Top management** for discussion, review and acceptance for incorporation into the quality management system via addition to our scope, or incorporation into customer requirements, operational activities, process controls, or escalation to the Risk and Opportunity Register for further analysis and mitigation.

1.4.5 Monitoring & Review

Each **Departmental Manager** in conjunction with the **Quality Manager** are responsible for the reassessment of their relevant interested parties. Reassessment is conducted on need-to-do basis, and includes:

1. Identifying new parties;
2. Reassessing each parties' requirement(s) and compliance status;
3. Adjusting mitigation plans or developing new mitigation plans;
4. Adjusting schedule and budgets, if applicable.

1.6 Applying QMS Processes

1.6.1 General

The *Process Matrix & Application* workbook provides the basis for programming internal audits as well as becoming a roadmap to the entire quality management system that allows internal and external personnel to clearly understand how our organization's processes fit together. The *Process Matrix & Application* workbook is prepared by the [Quality Manager](#) and submitted to [Top management](#) for discussion, review and acceptance.

1.6.2 Mapping Processes

[Your organization](#) uses the *Process Matrix* worksheet to map out and align the clauses and requirements of ISO 9001:2015 to the processes and functions within our organization. It provides a convenient overview of how the requirements relate to each management system process while helping to define the interaction between those processes. The [Quality Manager](#) are responsible for ensuring the *Process Matrix* worksheet is prepared, reviewed and kept up-to-date.

1.6.3 Process Application

[Your organization](#) uses the *Process Application* worksheet to assign requirements to relevant functions, processes, departments and teams to show how our organization establishes, implements, maintains and continually improves its management system, its processes and their interactions, in accordance with the requirements of ISO 9001:2015 Clause 4.4.1 and 4.4.2.

1.7 Forms & Records

All documentation and records generated by this procedure are retained and managed in accordance with the *Documented Information Procedure*.

Title & Description
Context & Interested Parties Analysis
Process Matrix & Application
SWOT Analysis Template
PESTLE Analysis Template