

Quality Procedure

Context of the Organization

Table of Contents

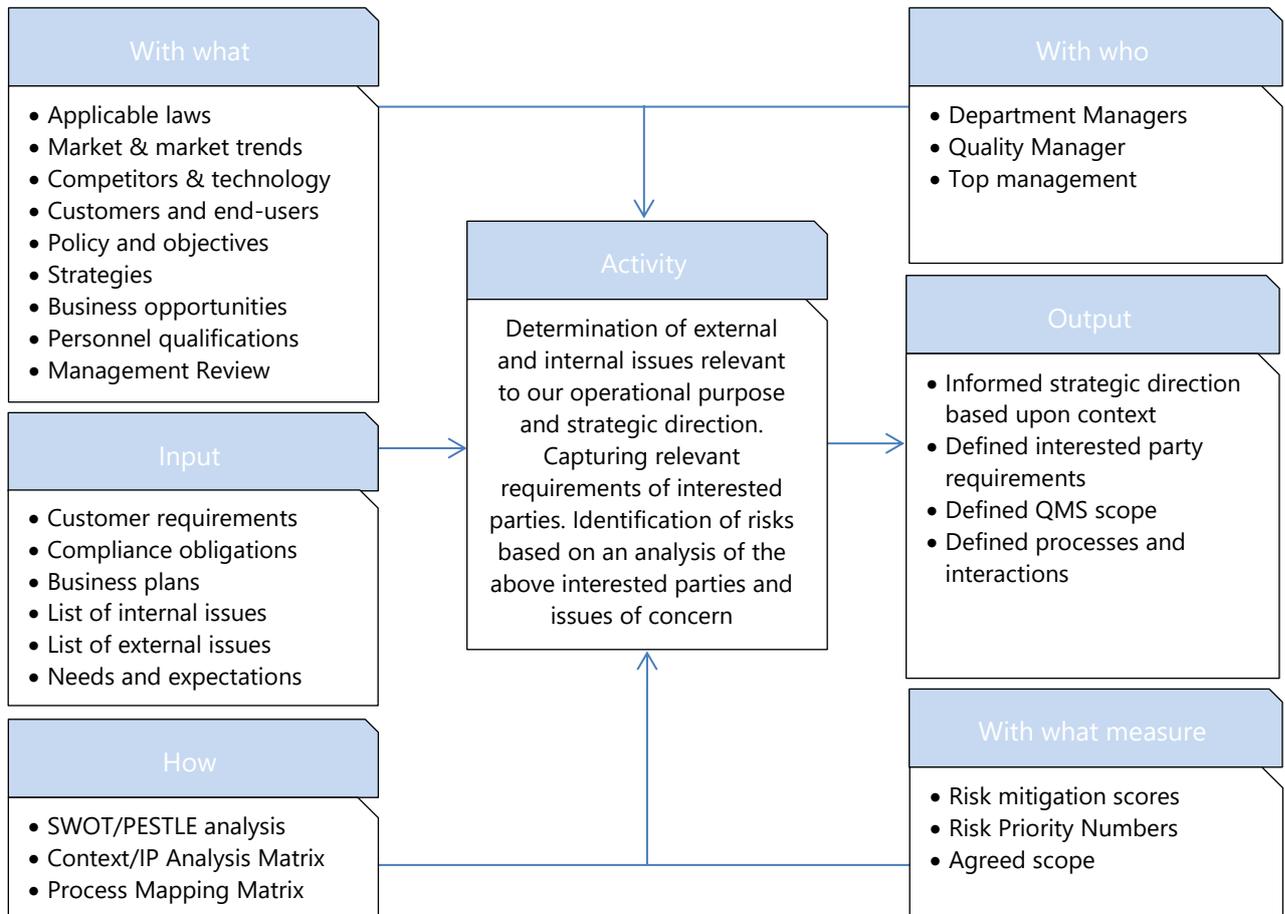
1 ORGANIZATIONAL CONTEXT	3
1.1 INTRODUCTION & PURPOSE.....	3
1.1.1 Process Turtle Diagram.....	3
1.1.2 References.....	3
1.1.3 Terms & Definitions	3
1.2 APPLICATION & SCOPE.....	4
1.3 RESPONSIBILITIES	4
1.4 UNDERSTANDING ORGANIZATIONAL CONTEXT	5
1.4.1 General.....	5
1.4.2 Capturing Internal Issues	5
1.4.2.1 Strengths.....	5
1.4.2.2 Weaknesses.....	6
1.4.2.3 Opportunities	6
1.4.2.4 Threats.....	6
1.4.3 Capturing & Analyzing External Issues.....	7
1.4.3.1 Political.....	7
1.4.3.2 Environmental	8
1.4.3.3 Technological	8
1.4.3.4 Social/Cultural.....	8
1.4.3.5 Legislative	8
1.4.3.6 Economic.....	9
1.4.4 Prioritizing Internal & External Issues.....	9
1.5 NEEDS & EXPECTATIONS OF INTERESTED PARTIES	9
1.5.1 General.....	9
1.5.2 Interested Party Requirements	10
1.5.3 Scoring Matrix	10
1.5.4 Action Matrix.....	10
1.5.5 Monitoring & Review	11
1.6 DETERMINING QMS SCOPE	11
1.6.1 General.....	11
1.6.2 Determining Scope.....	11
1.7 APPLYING QMS PROCESSES.....	12
1.7.1 General.....	12
1.7.2 Mapping Processes	12
1.7.3 Process Application.....	13
1.8 FORMS & RECORDS.....	13

1 Organizational Context

1.1 Introduction & Purpose

The purpose of this procedure is to outline **your organization's** process for the identification and determination of internal and external issues, interested party requirements, management system scope and processes that relate to our quality management system, and which influence our strategic direction (where we're going) and our operational purpose (what we make and do).

1.1.1 Process Turtle Diagram



1.1.2 References

Standard	Title	Description
BS EN ISO 9000:2015	Quality management systems	Fundamentals and vocabulary
BS EN ISO 9001:2015	Quality management systems	Requirements
BS EN ISO 9004:2018	Quality management systems	Guidelines for performance improvements

1.1.3 Terms & Definitions

Term	Definition
Interested party	Stakeholder that can affect, be affected by, or perceive itself to be affected by a decision or activity
Context	A combination of internal and external issues that can have an effect on an organization's approach to developing and achieving its objectives

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 Responsibilities

[Top management](#) are responsible for:

1. Determining the relevant external and internal issues:
 - a. That affect the ability to achieve the intended outcomes of the QMS;
 - b. That can impact on the planning of the QMS.
2. Assessing conditions capable of affecting or being affected by our organization;
3. Determining and communicating interested party requirements;
4. Determining strategic direction and operational purpose;
5. Determining the scope and boundaries of applicability;
6. Ensuring the policy and objectives are:
 - a. Compatible with the context;
 - b. Compatible with the strategic direction.
7. Implementing a process-based quality management system.

[Line Managers](#) and [Supervisors](#) are responsible for:

1. Identifying and listing the needs and expectations of any interested parties;
2. Analysing interested parties and their requirements;
3. Ranking the interested parties according to their degree of Priority and their Relevance;
4. Considering, developing and implementing stakeholder handling approaches;
5. Periodically reassessing their relevant interested parties;
6. Consulting Top management on applicable changes in the requirements of interested parties.

[Quality Manager](#) is responsible for:

1. Identifying and listing the needs and expectations of any interested parties;

2. Analysing interested parties and their requirements;
3. Ranking the interested parties according to their degree of Priority and their Relevance;
4. Considering, developing and implementing stakeholder handling approaches;
5. Updating Top management when changes occur;
6. Ensuring that context information is included for management review.

1.4 Understanding Organizational Context

1.4.1 General

Knowledge about [our organization's](#) context and the process by which it is obtained is underpinned by tools such as SWOT and PESTLE analysis. Only those issues that are relevant to our organization's operational purpose and strategic direction which effect; or have the potential to affect, our ability to achieve our objectives are captured using the *Context & Interested Parties Analysis* matrix and considered further.

1.4.2 Capturing Internal Issues

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

1. Organizational structure, and roles;
2. Policies and objectives;
3. Capabilities in terms of resources such as capital, human and technological;
4. Information systems;
5. Types of activities and exposure to hazards;
6. Location of where activities take place;
7. Relationships with, as well as perception of workers;
8. Contractual relationships such as outsourced activities;
9. Workforce characteristics including, quantity, experience, age, diversity;
10. Working conditions, organizational culture, working time arrangements and ergonomics;
11. Changes in products, processes, equipment;
12. Changes in any of the above factors.

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.

1.4.2.1 Strengths

Strengths are characteristics of our organization that allow operation more efficiently and effectively than competitors. We consider:

1. What our organization does well;
2. What advantages our business has over our competitors;
3. Our organizational structure and culture;
4. Strong partnerships with key suppliers;
5. Long term employees with important skills;