10 Quality Procedures

Schedule of Quality Procedures

Ref.	Title & Description	Turtle Diagram	Process Map
01	Context of the Organization Procedure	✓	x
02	Risk & Opportunity Procedure	✓	x
03	Objectives & Indicators Procedure	✓	x
04	Competence & Awareness Procedure	✓	✓
05	Documented Information Procedure	✓	✓
06	Non-conforming Outputs Procedure	✓	✓
07	Customer Satisfaction Procedure	✓	✓
08	Internal Audit Procedure	✓	✓
09	Management Review Procedure	✓	✓
10	Non-Conformity & Corrective Action Procedure	✓	✓

Quality Procedure

Context of the Organization

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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 (*Effects of influence*) = Priority x Relevance		**Priority** of Interested Party (*Effects on decisions*)			
		No importance	Minor importance	Some importance	Major importance
Relevance of Interested Party (*Effects on activities*)	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 (*Effects on decisions*)		
	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

Quality Procedure

Internal Auditing

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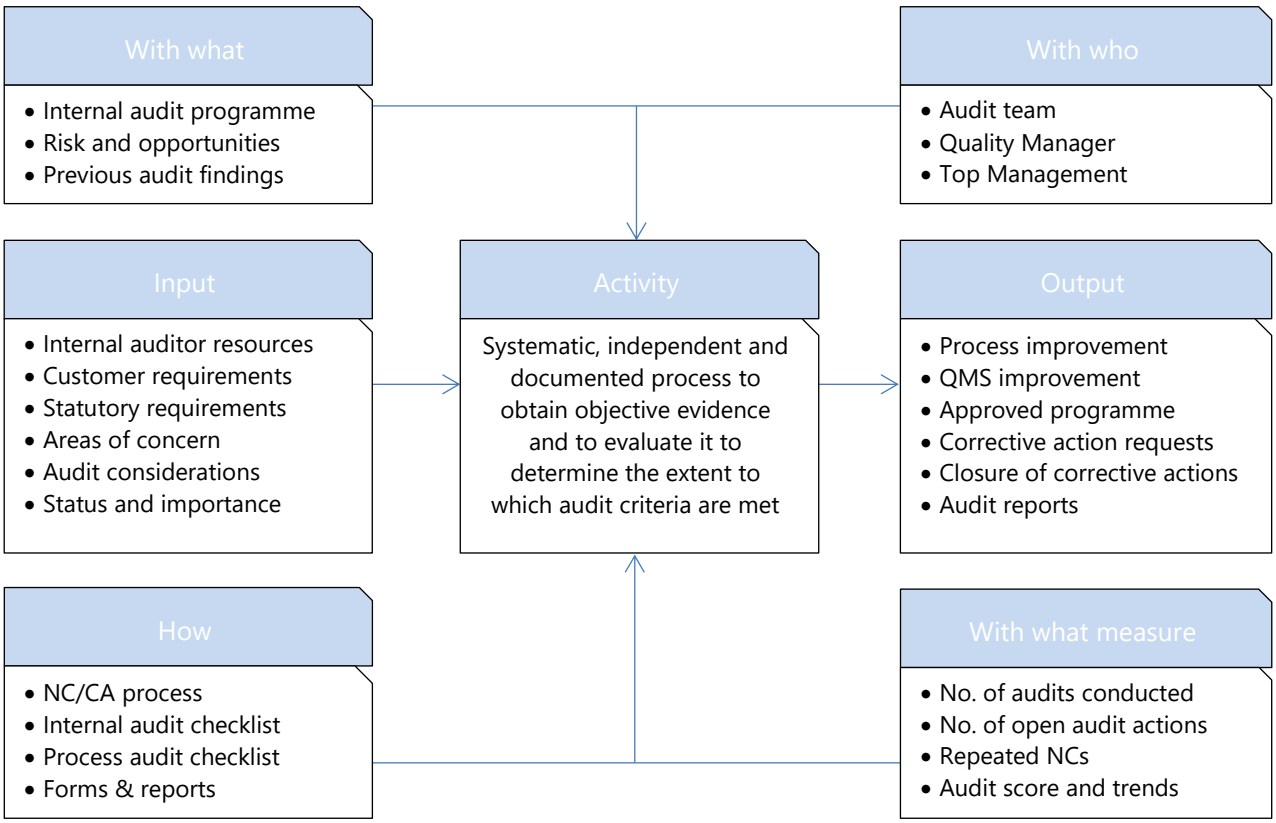
1 Internal Auditing

1.1 Introduction & Purpose

The purpose of this procedure is to define your organization's process for undertaking QMS audits, process audits, and supplier and legislation audits in order to assess the effectiveness of the application of our quality management system and its compliance to ISO 9001:2015. This procedure also defines the responsibilities for planning and conducting audits, reporting results and retaining associated records.

1.1.1 Process Activity Map



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
BS EN ISO 19011:2018	Auditing management systems	Guidelines for auditing

1.1.3 Terms & Definitions

Term	ISO 9000:2015 Definition
Conformity	Fulfilment of a requirement (3.6.4)
Non-conformity	Non-fulfilment of requirement (3.6.9)
OFI	Opportunity for improvement
Corrective action	Action to eliminate the cause of a non-conformity (3.6.9) and to prevent recurrence

1.2 Application & Scope

By applying the principles of auditing, outlined by ISO 19011:2018, your organization ensures that all internal audits are conducted with due professional care, integrity and independence. All conclusions derived from the audit are based upon objective and traceable evidence. Your organization's arrangements for conducting internal audits at planned intervals, include the following audit criteria:

1. Our own requirements, e.g. policies, processes, procedures, instructions, specifications;
2. Customer requirements, e.g. flowed down by contract;
3. Applicable external standards (including ISO 9001:2015).

1.3 Responsibilities

It is the responsibility of the Quality Manager to coordinate the internal audit programme in order to:

1. Obtain audit results;
2. Report audit performance;
3. Monitor trends, e.g. repeat audit findings or acknowledged improvement;
4. Determine the root causes of non-conformities;
5. Provide the results of audits to top management;
6. Track how long corrective actions remain open, versus planned closure;
7. Review the effectiveness of corrective actions taken.

The Internal Auditors are required to:

1. Review relevant management system documents and records;
2. Review and prepare the *Internal Audit Checklist*;
3. Arrange audit appointment;
4. Conduct opening meeting;
5. Sample and observe process inputs/activities/outputs;
6. Record objective evidence to verify process compliance or non-conformance;
7. Conduct the closing meeting;
8. Provide input for improvement of the audit programme and audit process.

The Auditees are required to undertake timely corrections to fix any immediate problems and corrective actions to prevent recurrence:

1. Ensure corrective actions are implemented and are closed-out within the agreed timeframe;
2. Minor areas of non-conformance are taken care of immediately;
3. Ensure the status of corrective actions and any non-conformances are kept up-to-date.

1.4 Internal Audit Process

1.4.1 Internal Audit Programme

The Quality Manager is required to prepare and distribute the *Internal Audit Programme* that is dependent upon the size and complexity of operations, including the identification and frequency of each audit, e.g. monthly, quarterly, annually:

1. Determine the status and importance of each process;
2. Establish audit frequency based on the status and importance of each process;

actions are completed. A member of the audit team will then sign off the audit report. An audit summary is prepared as an input for management review.

1.7 Forms & Records

All documentation and records generated by the internal audit process are retained and managed in accordance with the *Documented Information Procedure*. Retention of documented information to show that that the audit programme has been effectively implemented include the audit programme, audit plans, audit reports, questionnaires, audit evidence, corrective action, audit close out, auditor qualification, audit performance metrics.

Title & Description
Internal Audit Report.docx
Internal Audit Programme.xlsx (Includes the process matrix and the 10-year & 2-year audit programmes)
Gap Analysis Checklist.docx
Process Audit Template.xlsx
On-site Supplier Audit Checklist.docx
Off-site Supplier's Self-Assessment.docx
Internal Audit Checklist.xlsx
Corrective Action Report.docx
Corrective Action Log.xlsx