Integrated Manual & Policy Template

ISO 9001:2015 & ISO 14001:2015

Contents

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

SWOT analysis provides our organization with a 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 a 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 that only a limited set of their respective needs and expectations apply to our operations or our EQMS. Such needs and expectations broadly include those shown in the figure below.

Figure 2: Interested Parties and Their Needs and Expectations

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.

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 that become inputs to our EQMS and to our product and service designs.

4.3 Management Scope

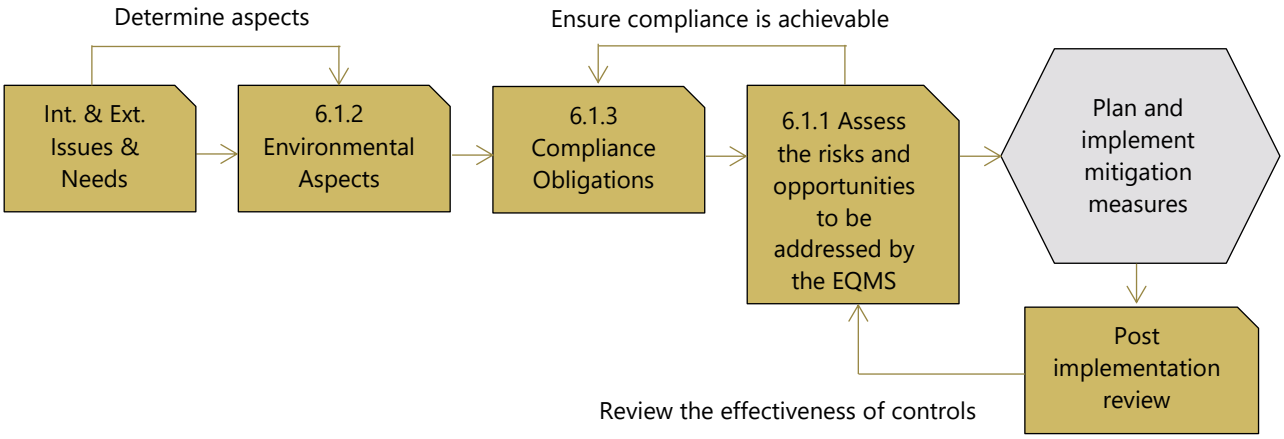
Based on the analysis of the issues and requirements identified in Sections 4.1 and 4.2, your organization has established the scope of our EQMS in order the implement our objectives and the policies relevant to our context, compliance obligations, the life cycle perspective of our products and activities, and our authority and ability to exercise control and exert influence over our environmental aspects.

6 Planning

6.1 General

In order for our organization to have a successful EQMS, we consider and manage the risks and opportunities relating to our stakeholders, our external and internal context, and our quality and environmental aspects. This process uses the information collected during our context evaluation (SWOT & PESTLE), stakeholder and interested party analysis, and the evaluation of our aspects.

Figure 4 Sources of Risk & Opportunity



Top management then considers the risks and opportunities that we manage to ensure that our EQMS meets its intended outcomes, manages external environmental conditions, and achieves continual improvement.

Once the significant or material risks and opportunities are identified, our organization plans actions to mitigate perceived risks or take advantage of opportunities. Action is taken in a variety of ways using our EQMS system processes via setting objectives, targets, policies, operational control or emergency preparedness, supplier evaluation, or other business processes.

6.1.1 Risks & Opportunities

The 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 mitigate risks.

Top management is responsible for incorporating risk-based thinking into our organization's culture. This includes the establishment of risk management policies and targets to ensure the effective implementation of risk and opportunity management principles throughout the lifecycle of our products, activities, or services 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 is communicated by the *Risks & Opportunities Procedure* which includes a methodology for 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.

Score	New Supplier	Currently Approved Supplier
>86%	Systems are effective; start doing business with this supplier	No change in status, systems are effective, continue business with this supplier
85%	Conditionally approve the supplier, and encourage them to improve their processes	Request improvement, encourage them to improve their processes, and monitor and continue using the supplier
60-85%	Supplier may implement corrective actions and request re-audit	Request immediate corrective action and request re-audit, temporarily stop using issues are fixed
<59%	There are serious problems and or defects that could impact our business, reject the supplier	There are serious problems and or defects impacting our business, change supplier

Poor-performing suppliers are replaced, and the *Approved Supplier Index* is updated. The frequency of supplier contract reviews varies depending on their performance and the criticality of the products supplied, but the interval between each review is no more than 12 months.

The type and extent of control required for purchased products depends on the effect of the purchased product on the subsequent realization of the end product. To ensure that all purchase order requirements are met before the material is released for use, purchased items and delivery notes are checked against the purchase order to confirm that the identity and quantity are correct. Activities to verify conformance to requirements may include:

1. Obtaining evidence of quality conformance from the supplier in the form of inspection documentation, certificates of conformity, test reports and/or record of statistical process control;
2. Inspection and audit at supplier's facilities;
3. Review and acceptance of required documentation;
4. Inspection of product upon receipt;
5. Verifying test report data against applicable specifications;
6. Periodic third-party testing may be performed on materials to verify the accuracy of supplied test reports.

All purchased product inspections are recorded on the *Receiving Inspection Log* and retained along with copies of any applicable conformance information described above. Satisfactory purchased items are placed in stock. In the event that items are rejected on receipt, a nonconformance report is raised, and the supplier is contacted to arrange replacement or credit.

Where a purchased product is released for production, pending completion of all required verification activities, it is identified and recorded to allow recall and replacement if it is subsequently determined that the purchased product does not meet requirements.

8.4.3 Purchasing Information

Your organization uses purchase orders to describe the product or service to be purchased. Designated individuals within the company create purchase orders using the company system. They also ensure the adequacy of the requirements that are specified by the purchase order before release. Each purchase order includes, where appropriate:

1. Identification of product or service to be delivered, quantity, delivery date, and cost;
2. Requirements for approval or qualification of product, procedures, processes, or equipment;

The audit frequency is also based upon process performance trends, results from previous audits, levels of customer satisfaction, rates of nonconformity and corrective action, etc., to ensure that our organization focuses on the aspects that affect product and process conformity the most. The criteria, scope, frequency, and methods of each audit are defined in the audit reports.

The audit is conducted according to the *Internal Audit Procedure* to ensure that timely corrective actions are implemented to correct any deficiencies found. The results of the audits are recorded and submitted to the personnel having responsibility in the area audited. The results of the internal quality audits are summarized for discussion at management reviews.

Supporting documentation:

Doc No.	Title & Description
P0920-01	Internal Auditing Procedure

9.3 Management Review

9.3.1 General

To ensure the continuing suitability, adequacy and effectiveness of our EQMS in meeting our organization's strategies, Top management conducts formal management review meetings at planned internals. The requirements for conducting a management review are defined and communicated using the *Management Reviews Procedure*.

Each management review meeting may require multiple subjects and departmental input and rely upon multiple metrics and data analysis. When more frequent meetings are conducted, the meeting agenda is reduced to focus on customer-critical issues, with the full review cycle of the EQMS occurring annually.

Agenda Item (9.3.2)	Impact on Customer or Business	Frequency	Type of Meeting
Previous actions	High	Monthly	Functional review
Changes to the EQMS	Low	Six-monthly	EQMS review
Performance of the EQMS	Very High	Weekly/Daily	EQMS review
Environmental aspects	High	Monthly	Environmental review
Customer satisfaction	High	Monthly	Functional review
Objectives	Medium	Quarterly	Planning review
Compliance obligations	Low	Six-monthly	Environmental review
Product/Process conformity	Very High	Weekly/Daily	Quality review
NCR/CAR/SCAR root-causes	Medium	Quarterly	Planning review
Monitoring and measurement results	Very High	Weekly/Daily	EQMS review
Internal audit results	Low	Six-monthly	EQMS review
External providers	Medium	Quarterly	Planning review
Resources required	Medium	Quarterly	Planning review
Actions to address risk	Low	Six-monthly	EQMS review
Improvement actions	High	Monthly	Functional review

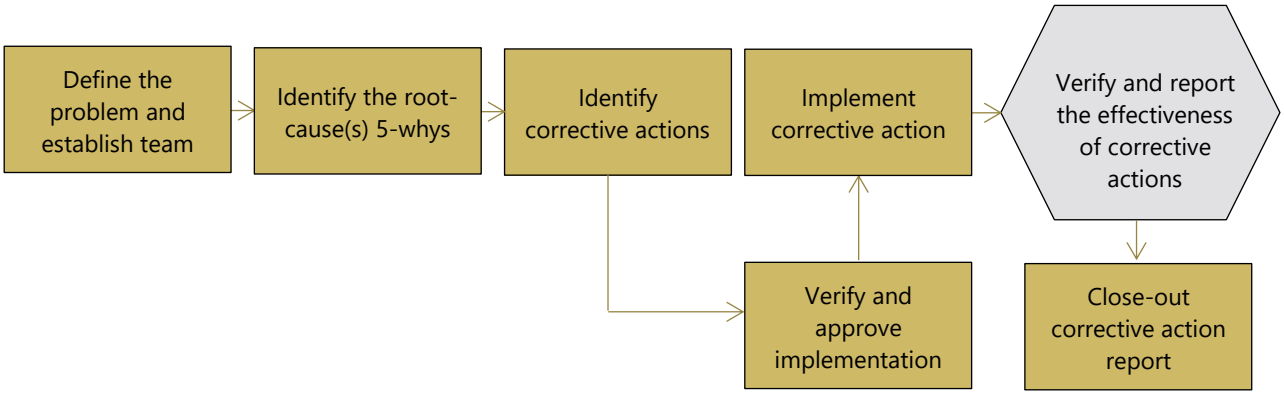
In response to changing or special conditions and events, the frequency of management review activities will increase.

In summary, a Senior Director chairs the EQMS Review Meeting. The review group is coordinated and recorded by the EQMS Manager. To ensure that the review group includes each of the requirements of ISO 9001:2015

1. **Processes producing negative results and defective outputs**. Any process which does not produce an acceptable product or services should be reported by any employee through the initiation of the Corrective Action Request (CAR) form;
2. **Incoming products from Suppliers or Customers**. Recurring problems with discrepant materials from a vendor are reported to the Purchasing Manager, and then the Supplier Corrective Action Request (SCAR) form is completed and submitted;
3. **Services provided by external sources**. If a service provided from an external source does not comply with the requirements of the purchase order and/or contract, then the Supplier Corrective Action Request (SCAR) form is completed and submitted;
4. **Internal issues and quality audits**. During routine internal quality audits and inspections, processes, procedures, and work instructions may be identified as nonconforming. These are documented in the Internal Audit Report form initially and the Corrective Action Request (CAR) form.

This process focuses on satisfying ISO 9001 Clause 10.2, which requires our organization to evaluate the need for *corrective action* that will prevent the recurrence of nonconformities. While ISO 9001 Clause 8.7 requires our organization to *correct* product outputs that fail to conform to specified requirements during manufacture and after distribution and is covered by a separate procedure.

Figure 9: Nonconformity & Corrective Action Process



The appropriate manager documents the nonconformity using the *Nonconformance Report* and considers the root-cause of the nonconformity. If necessary, other responsible parties will be consulted to identify the root cause and plan appropriate action.

The EQMS Manager records the report together with any agreed corrective action within the *Corrective Action Log*. The results of the corrective action are recorded within the *Corrective Action Report*.

Potential root-causes that are under our control are validated. Your organization applies the following validations to our answers for root-causes by asking the following questions for every possible root-cause identified at all levels of the 5-Whys:

1. Is there any proof, something you can measure or observe, to support the root-cause determination?
2. Is there any history or knowledge to indicate that the possible root-cause could actually produce such a problem?
3. Is there anything 'underneath' the possible root-cause that could be a more probable root-cause?
4. Is there anything that this possible root-cause requires in order to produce the problem?
5. Are there any other causes that could possibly produce the same problem?