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Quality Management System Manual

ISO 9001:2015

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2 Introduction

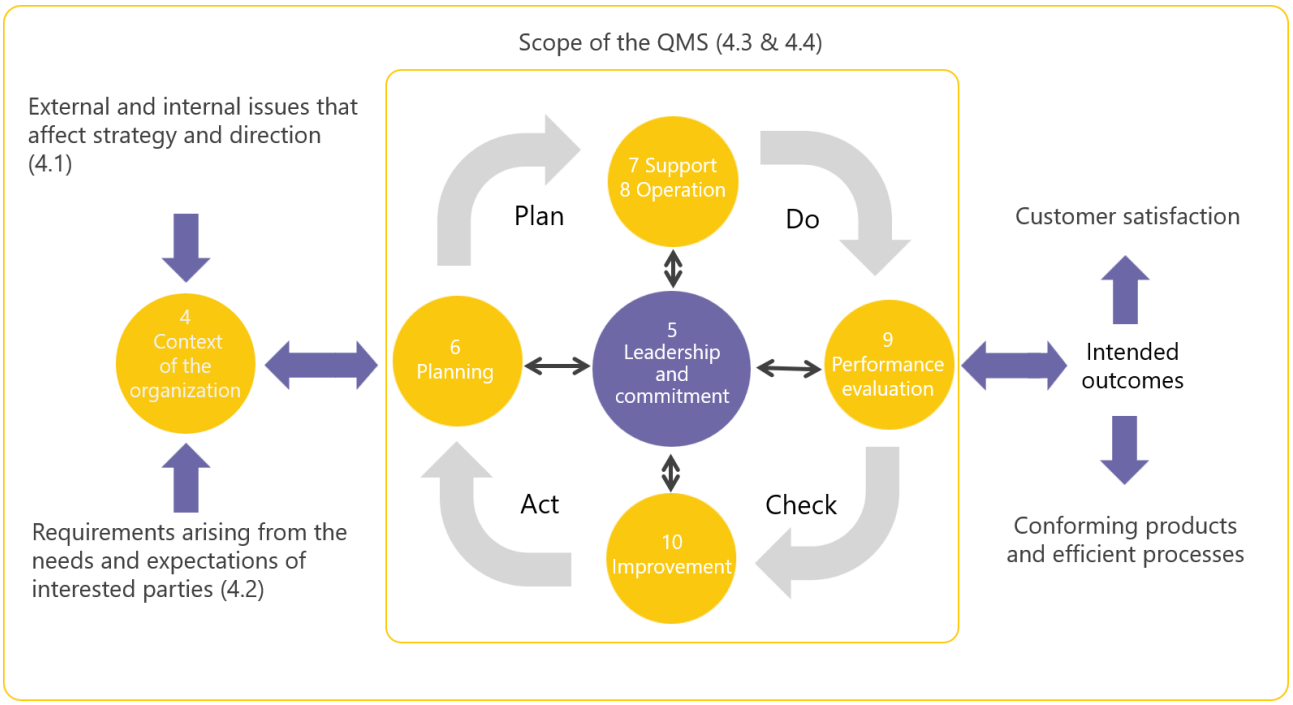
Your organization has developed and implemented a quality management system (QMS), which uses ISO 9001:2015 as a framework that allows our organization to document and improve our practices to better satisfy the needs and expectations of our customers, stakeholders, and other interested parties.

2.1 Process Activity Map

The process overview (turtle diagram) provides stakeholders, process owners, and participants with an overview of the interactions of the management system.

The figure below illustrates our methodology for developing our quality management system, using the plan, do, check, and act process approach to implement and deliver management system objectives and stakeholder requirements to achieve compliance.

Figure 1: Overview of the Quality Management System



Certification to ISO 9001 will help achieve these intended outcomes and demonstrate that the quality management system effectively provides value for our organization and its interested parties.

2.2 Purpose

This document describes our quality management system and delineates authorities, interrelationships, and the responsibilities of personnel within the system. The quality manual also references the procedures and activities comprising our management system.

The document is used to familiarise customers and other external organizations or individuals with the quality controls that your organization has implemented. The controls defined herein demonstrate to all interested parties that our management system is focused on implementing processes that deliver customer satisfaction and process efficiency.

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The output from this activity is evident as an input to consider risks and opportunities and the actions we take to address them. For more information about our risk and opportunity management framework, refer to Section 6.1.

Although we acknowledge that ISO 9001 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 that describes our organizational context:

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.

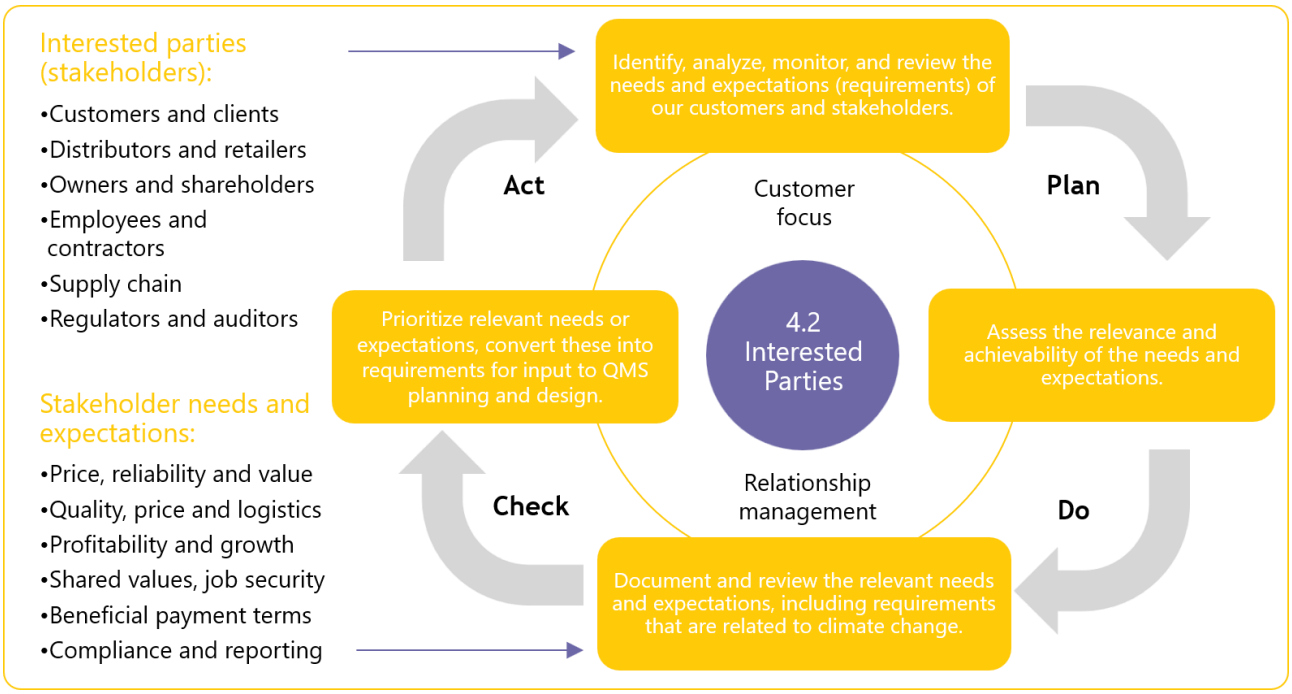
SWOT analysis provides our organization with a framework for reviewing and evaluating our strategies, the position and direction of our organization, business propositions, and other ideas.

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, some of which relate to climate change, will develop over time and that only a limited set of their respective needs and expectations apply to our operations, or the quality management system. Such needs and expectations broadly include those shown in the figure below.

Figure 3: Interested Parties and Their Needs and Expectations



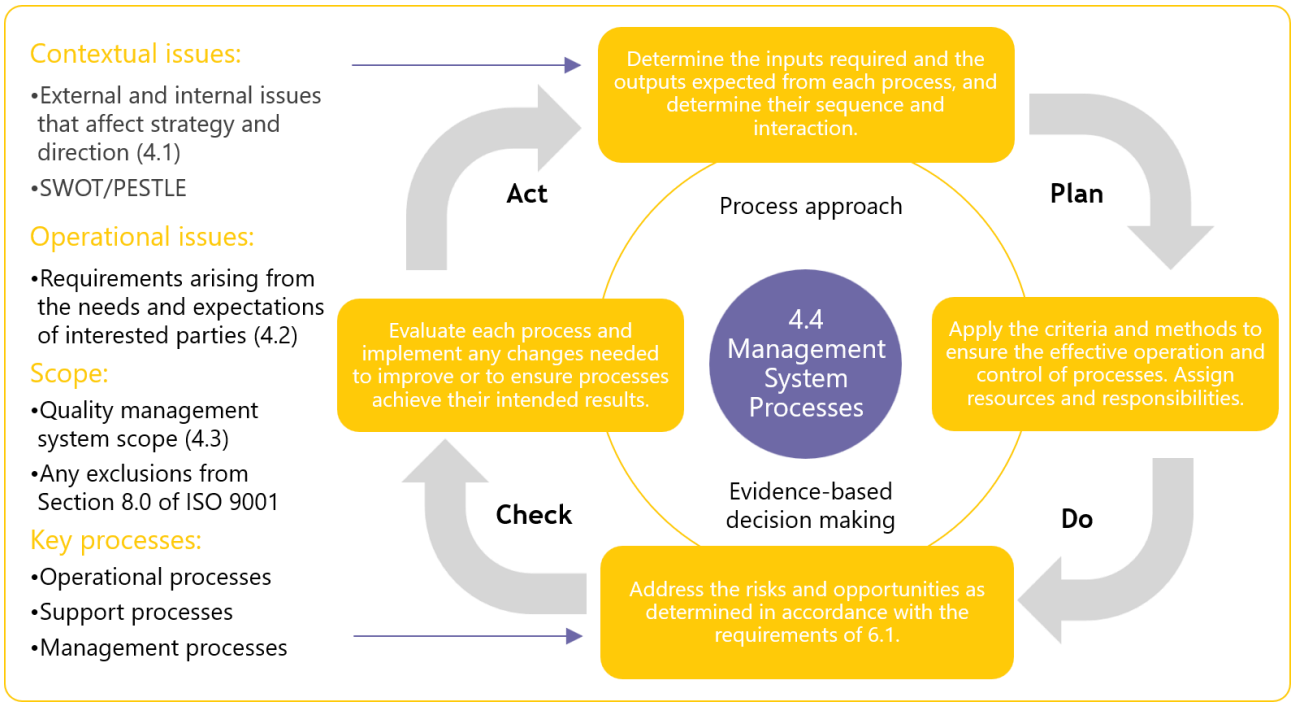
4.4 Management System Processes

Your organization has implemented the quality management system in a broader management landscape. It has established, documented, and implemented our processes, policies, and objectives while satisfying the requirements of ISO 9001.

To achieve this, your organization has adopted the process approach advocated by ISO 9001:2015 and ISO 9000:2015. Using the PDCA cycle to manage processes and stimulate improvement, we have incorporated the 'process approach' into our daily operations.

Risk-based thinking is applied when developing, implementing, and improving the effectiveness of our quality management system.

Figure 4: Process Approach



We establish and maintain system effectiveness by defining key process groups and managing their inputs, activities, controls, outputs, and interfaces. Refer to **Appendix A.1**, which shows the interaction of the process groups within our quality management system.

Monitoring key performance indicators (KPIs) linked to our objectives is used to measure, monitor, and communicate process performance. This approach allows top management to regularly review quality management system performance and ensure its ongoing integration with business processes.

As part of the decision-making process, we use trends and statistical data and trends related to nonconformities, customer feedback, targets, objectives, and corrective actions, as well as monitoring and measurement results, audit results, levels of customer satisfaction, process performance data and compliance data, to ensure that objective management decisions can be made.

By managing the inputs, activities, controls, outputs, and interfaces, our organization ensures that management system effectiveness is established, monitored, maintained, and improved. The process landscape is described

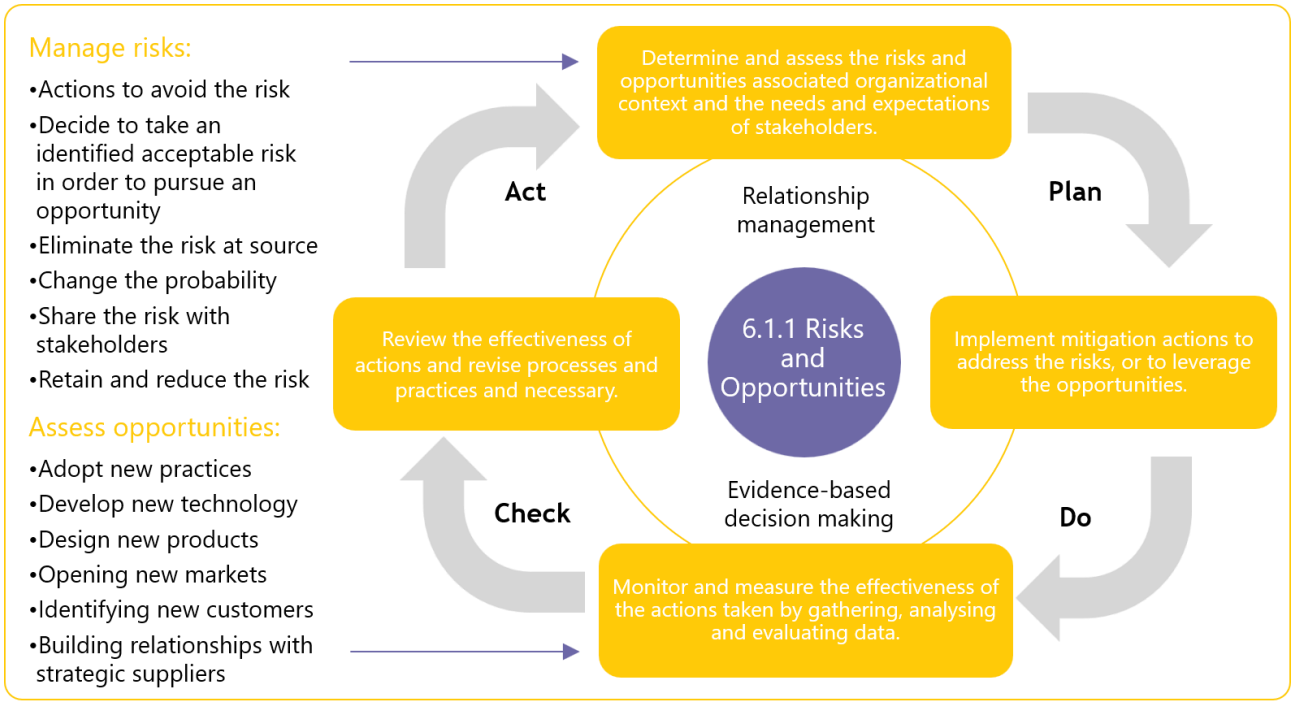
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6 Planning

6.1 Actions to Address Risks & Opportunities

To have a successful quality management system, we consider and manage the risks and opportunities relating to our stakeholders and our organization's external and internal contexts. This process uses the information collected during our context and strategy evaluations (via SWOT & PESTLE analysis) and stakeholder and interested party analysis.

Figure 6 Risk & Opportunity Process



Top management then considers the risks and opportunities we manage to ensure that our quality management system 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 various ways using our quality management system processes via setting objectives, targets, and policies, developing operational controls, and undertaking supplier evaluations.

6.1.1 Risks & Opportunities

Risk and opportunity management within your organization aims to ensure that organizational capabilities and resources are employed efficiently and effectively 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;

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and reporting this data to top management. Our identified quality risks and opportunities are used to prioritize which objectives and plans to implement.

Top management is responsible for agreeing on objectives and targets relating to activities under their control and for approving and endorsing objectives and targets for the organization. Planning for action to mitigate adverse risk and the leveraging of opportunities is implemented via:

1. Quality objectives;
2. Monitoring, measuring, and analysis;
3. Operational controls;
4. Others, as appropriate.

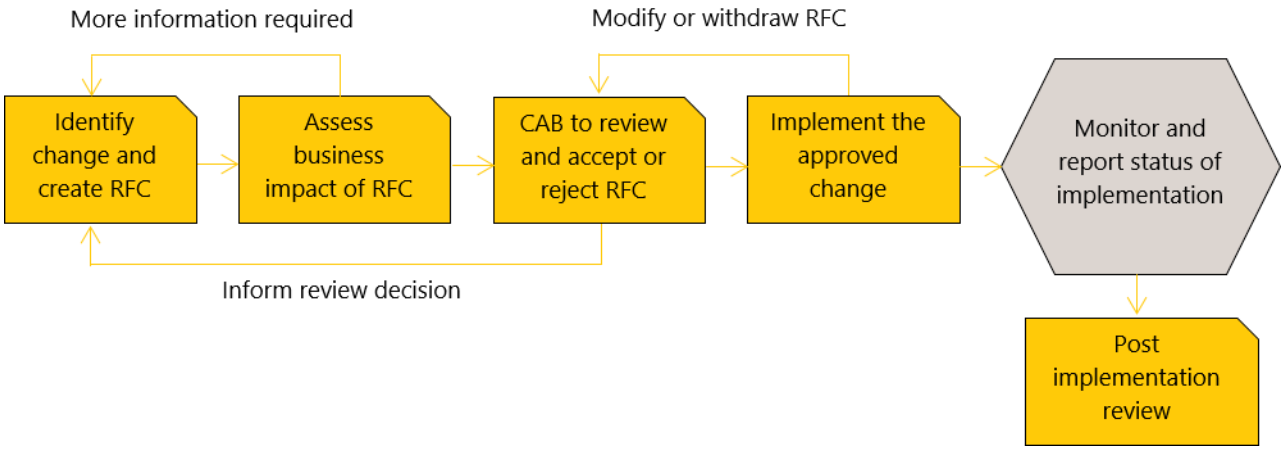
The programme acts as our management action plan that identifies individual objectives, the means by which the objectives are to be achieved, and the timeframe in which the actions are to be achieved. Actions are assigned to suitably authorized and responsible members of the management team, who are responsible for ensuring that the actions are completed within the terms specified by the programme.

Regular and documented management reviews make recommendations to ensure that those risks and opportunities that could affect the intended outcomes of the quality management system are considered and planned for via the most appropriate business processes.

6.3 Planning for Change

Our management system is planned and implemented to meet our corporate objectives and the requirements of ISO 9001. Planning involves establishing and communicating our corporate policies, objectives, and associated operational procedures.

Figure 7: Change Management Process



This document constitutes our overall plan for establishing, maintaining, and improving our management system. For each instance of management system planning, the output is documented and retained accordingly.

Any changes are controlled to ensure that no unintended threats affect the quality management system, and they are documented and assessed using the *Risk & Opportunity Register*.

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The type and extent of control applied to our suppliers and the purchased product depend on the effect the outsourced product or service may have on our final product or service. The following considerations are taken into account:

1. Ensuring that we understand the capabilities and competencies of potential outsourcing suppliers;
2. Ensuring that we communicate the roles and responsibilities of the outsourcing supplier;
3. Defining the quality requirements for the outsourced process, activity, or product;
4. Establishing upfront the criteria for and review of deliverables, frequency of inspections and audits;
5. Selecting and qualifying appropriate outsourcing suppliers;
6. Ensuring usage requirements, precautions, and protective measures are communicated and available.

After successful review and evaluation, suppliers are evaluated and added to the *Approved Supplier Index*. It is the responsibility of the Purchasing Manager to evaluate and select suppliers based on their ability to supply products or services in accordance with specified QMS requirements to ensure that our operations remain compliant with our:

1. Corporate QMS policies and objectives;
2. Sustainable development procurement policy;
3. Legal and other requirements.

Additionally, other internal resources may be called on to assist as required. The selection, evaluation, and re-evaluation criteria are defined and communicated in the *Suppliers & Purchasing Procedure*. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

8.4.2 Purchasing Controls

Your organization ensures that externally provided processes, products, and services do not adversely affect our ability to consistently deliver conforming products and services to our customers. Quality control measures are applied to outsourced processes and purchased products where appropriate. These controls are documented within the purchasing information and communicated to the supplier.

A SCAR Form is issued to Suppliers and vendors for repetitive, ongoing problems and issues that significantly impact end-product delivery. A SCAR may be requested due to the supplier's poor performance for more than three consecutive months or any three months in 12 months based on data analysis.

Supplier performance and capability are monitored and assessed through periodic, 2nd party audits, performance data analysis, and inspection and/or verification of the purchased product or outsourced process. Suppliers who demonstrate inadequate audit and delivery performance must implement corrective actions.

Personnel with authority to take action on the remediation are identified in the report. The Supplier's approval status will be determined based on the table below:

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

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2. **First-article inspection and testing** – Typically, the first produced unit that both the customer or supplier agrees to use as the required base-line standard for all following units;
3. **In-process inspection and testing** - Products are withheld from further processing until there is objective evidence that the required inspection and test have been performed;
4. **Final inspection and testing** - Evidence that all inspections and tests that were required during previous stages of manufacturing were performed and documented as meeting the requirements.

Measurement and acceptance criteria that are necessary for product acceptance are retained as documented information; subsequent acceptance records form the production documentation evidence, which includes the following information:

1. Criteria for acceptance and rejection;
2. Locations in the process sequence where measurement and testing operations were performed;
3. Types of measurement instruments used, including any instructions associated with their use;
4. Test records showing actual test results where required by the specification or acceptance test plan.

Documented information is retained to indicate the person authorizing the release of the product. Product release and service delivery do not proceed until all the planned arrangements have been satisfactorily completed unless otherwise approved by a relevant authority and, where applicable, by the customer.

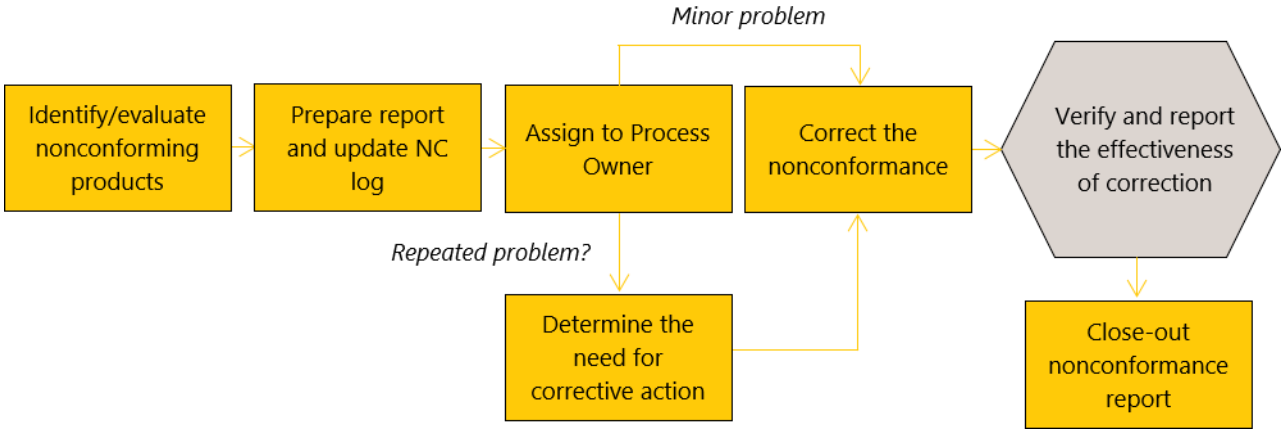
Supporting documentation:

Doc No.	Title & Description
P0860-01	Testing & Inspection Procedure

8.7 Nonconforming Outputs

Your organization ensures that provisions are made for identifying and controlling all nonconforming outputs and materials, including nonconforming product returns by a customer, to prevent the inadvertent use or shipment of nonconforming products and the unnecessary costs associated with the processing of nonconforming products.

Figure 8: Nonconforming Outputs Process



The *Nonconforming Outputs Procedures* define the responsibilities, authorities, and methods used for the identification, segregation, review, and disposition of nonconforming products, as well as the implementation of corrective action to prevent the recurrence of the nonconformance and action appropriate to the effect, or

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Internal auditors are selected to ensure objectivity and impartiality of the audit process. This is achieved by selecting a team of auditors from cross-functional departments who have received the appropriate training in the auditing process. The following qualitative scoring criteria are used to identify the level of compliance and effectiveness during internal audits:

Finding	Criteria Description
Conforms	Audit findings indicate conformity (3.6.11). See ISO 9000:2015. Conforms [+100]. Criteria: All performance indicators, metrics, objectives, audit results, etc., show stability and consistently achieve targets. The process is fully documented and implemented and demonstrates compliance and effectiveness. Continue to monitor trends and indicators to determine ongoing stability.
Minor NC	Audit findings indicate a nonconformity (3.6.9). See ISO 9000:2015. Minor [-25]. Criteria: Poor performance, adverse trends, expected results not achieved. Current practices conform but are not documented. Deviation from practice is unlikely to result in the failure of the QMS or process or will not result in the delivery of nonconforming products. Investigate root cause (s) and implement corrective action by the next reporting period or next audit.
Major NC	Audit findings indicate a nonconformity (3.6.9). See ISO 9000:2015. Major [-75]. Criteria: Practices are nonconforming and likely to cause compliance issues. Likely to have a significant adverse effect on customer satisfaction, product quality, delivery, or profitability. Process not implemented or documented. Implement immediate containment action, investigate root cause (s), and apply corrective action. Re-audit in 4 weeks.
OFI	Opportunities for improvement (3.3.1) See ISO 9000:2015 or recording good practices. (3.10) Note 2 ISO 19011:2018. Minor problems exist, with weaknesses, bottlenecks, or potential deficiencies, which, if not improved, may lead to nonconformity in the future. The auditor noted negative or positive situations but did not relate to a requirement in the standard.

The Quality Manager coordinates all external audits; the relevant findings will be input for the improvement phase. External audits such as statutory fire inspections, reviews, evaluations, and compliance audits may be carried out by external bodies, such as the Health and Safety Executive (HSE) or Notified Body. When such external audits occur, whether planned or unannounced, the Quality Manager will accompany external auditors.

9.2.2 Internal Audit Programme

The internal audit programme, coordinated by the Quality Manager, details the frequency and general focus of each internal audit and is recorded and communicated within the *Internal Audit Programme*. Your organization's internal audit programme is based upon a strategy that considers the status and importance of each process comprising the quality management system.

The audit frequency is also based on 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 internal audit reports define each audit's criteria, scope, frequency, and methods. The selection of trained auditors and their subsequent impartial conduct ensures objectivity throughout the audit process and that:

1. The results of each are reported to the Quality Manager;
2. That timely, appropriate corrective action is undertaken where required;
3. They retain documented information such as audit checklists and audit reports as evidence of the effective implementation of the audit programme with respect to each audit.

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