QMS Manual - Manufacturing

ISO 9001:2026 Edition

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QMS Manual - Manufacturing

ISO 9001:2026 Edition

Contents

1 Approvals & Revision History 4
1.1 Approvals 4
1.2 Revision History 4
1.3 Proprietary Information 4
2 Introduction 5
2.1 Process Activity Map 5
2.2 Purpose 5
2.3 Applicability 6
2.4 Process Approach 6
2.5 Plan-Do-Check-Act Cycle 6
2.6 Management System Principles 6
3 Terms & Definitions 7
4 About Our Organization 8
4.1 Organizational Context 8
4.2 Relevant Interested Parties 9
4.3 Management System Scope 10
4.4 Management System Processes 11
5 Leadership 13
5.1 Leadership & Commitment 13
5.1.1 General 13
5.1.2 Customer Focus 14
5.2 Management System Policy 14
5.2.1 Establishing the Policy 14
5.2.2 Communicating the Policy 15
5.3 Roles, Responsibilities & Authorities 15
5.3.1 Top Management 16
5.3.2 Quality Manager 16
5.3.3 Quality Coordinators 17
5.3.4 Managers & Supervisors 17
5.3.5 Employees & Contractors 17
6 Planning 19
6.1 Actions to Address Risks & Opportunities 19
6.1.1 Determining Risks & Opportunities 19
6.1.2 Action to Address Risks 20
6.1.3 Action to Address Opportunities 21
6.2 Objectives & Planning to Achieve Them 21

SAMPLE

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6.2.1 Quality Objectives 21
6.2.2 Planning to Achieve Objectives 23

6.3 Planning for Change 24

7 Support 26

7.1 Resources 26
7.1.1 General 26
7.1.2 People 26
7.1.3 Infrastructure & Natural Resources 26
7.1.4 Operational Environment 27
7.1.5 Monitoring & Measurement Tools 27
7.1.6 Organizational Knowledge 28

7.2 Competence 29

7.3 Awareness 30

7.4 Communication 30
7.4.1 General 30
7.4.2 Internal Communication 31
7.4.3 External Communication 31

7.5 Documented Information 32
7.5.1 Management System Documents 32
7.5.2 Creating, Updating & Issuing 32
7.5.3 Controlling Documented Information 32

8 Operations 34

8.1 Operational Planning & Control 34

8.2 Determining Requirements for Products 34
8.2.1 Customer Communication 34
8.2.2 Determining Requirements 35
8.2.3 Review of Requirements 35
8.2.4 Changes in Requirements 35

8.3 Design & Development 36
8.3.1 General 36
8.3.2 Planning 36
8.3.3 Inputs 37
8.3.4 Controls 37
8.3.5 Outputs 38
8.3.6 Changes 38

8.4 Suppliers & Purchasing 39
8.4.1 General 39
8.4.2 Purchasing Controls 39
8.4.3 Purchasing Information 41

8.5 Production Provision 42
8.5.1 Control of Production Provision 42
8.5.2 Identification & Traceability 43
8.5.3 Property Belonging to Customers or External Providers 44
8.5.4 Preservation 44

SAMPLE

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8.5.5 Post-delivery Activities 45
8.5.6 Control of Changes 45
8.6 Release of Products 46
8.7 Nonconforming Outputs 46
9 Performance Evaluation 48
9.1 Monitoring, Measurement, Analysis & Evaluation 48
9.1.1 General 48
9.1.2 Customer Satisfaction 48
9.1.3 Analysis & Evaluation 49
9.2 Internal Audit 50
9.2.1 General 50
9.2.2 Internal Audit Programme 51
9.3 Management Review 52
9.3.1 General 52
9.3.2 Inputs 53
9.3.3 Results 54
10 Improvement 56
10.1 Continual Improvement 56
10.2 Nonconformity & Corrective Action 57
10.2.1 Corrective Action 57
10.2.2 Supplier Corrective Action 58
Appendices 60
A.1 Interaction of Processes 60
A.2 Organization Chart 61
A.3 Correlation Matrix 62

1 Approvals & Revision History

1.1 Approvals

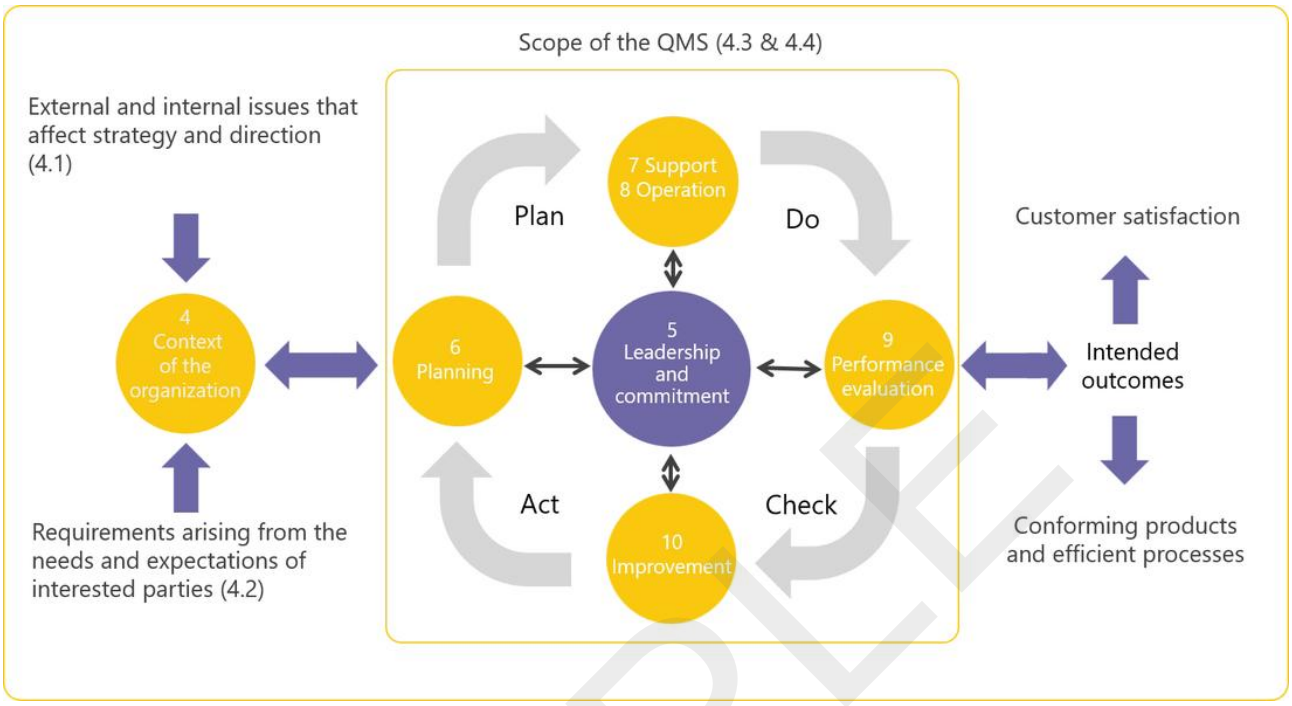
The signatures below certify that this management system manual has been reviewed and accepted and demonstrate that the signatories are aware of all the requirements contained herein and are committed to ensuring their provision.

	Name	Signature	Position	Date
Prepared by				
Reviewed by				
Approved by				

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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 familiarize customers and other external organizations or individuals with the quality controls that our 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.

2.3 Applicability

Our quality management system meets the requirements of ISO 9001:2026 and uses the Plan, Do, Check, and Act approach to process planning. Our management system addresses and supports our strategies for the <design, development, manufacturing, installation, and servicing of our products>, <also insert the registered address of your organization and/or facilities here>

The following table identifies any non-applicable ISO 9001:2026 requirements and provides a brief narrative to justify their omission from the scope of our management system:

Clause	Justification for Exclusion
8.3	For example, we exclude design and development, as we do not design or modify components.

2.4 Process Approach

Your organization fosters the use of a process approach during the development and implementation while improving the effectiveness of the quality management system. The application of the process approach enables:

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PESTLE analysis per ISO 9001:2026 Clause 4.1. They are recorded in the context register where they are relevant to the QMS.

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 available 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.

To ensure that our products and processes 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 address their relevant needs and expectations as inputs to our management system and product designs.

For each relevant interested party, we determine which of their requirements will be addressed through the quality management system (ISO 9001:2026 Clause 4.2). This determination is recorded in the Interested Parties Register (F0420-01) and is monitored and reviewed as the needs and expectations of interested parties change.

Prioritized relevant needs or expectations are converted into requirements, which become inputs to quality management system planning and product designs. The outputs from this process are typically used to inform the following sections and processes of this document:

1. Management system scope - 4.3;
2. Management system processes - 4.4;
3. Risks and opportunities - 6.1;
4. Communication - 7.4;
5. Operations - 8.0.

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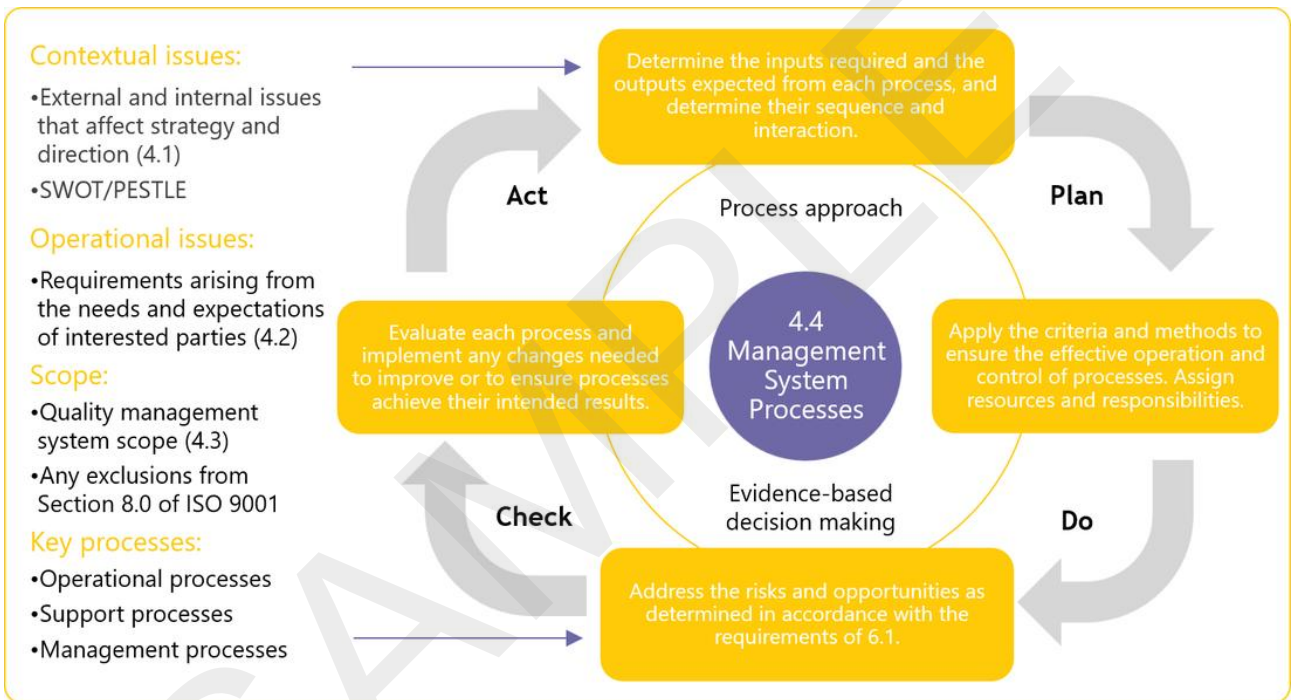
4.4 Management System Processes

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

To achieve this, our organization has adopted the process approach advocated by ISO 9001:2026 and ISO 9000:2026. 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 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 and reported using documented procedures, process maps, turtle diagrams, matrices, schedule charts, etc. The process landscape is defined by three key process groups and their sub-processes, as shown in the table below.

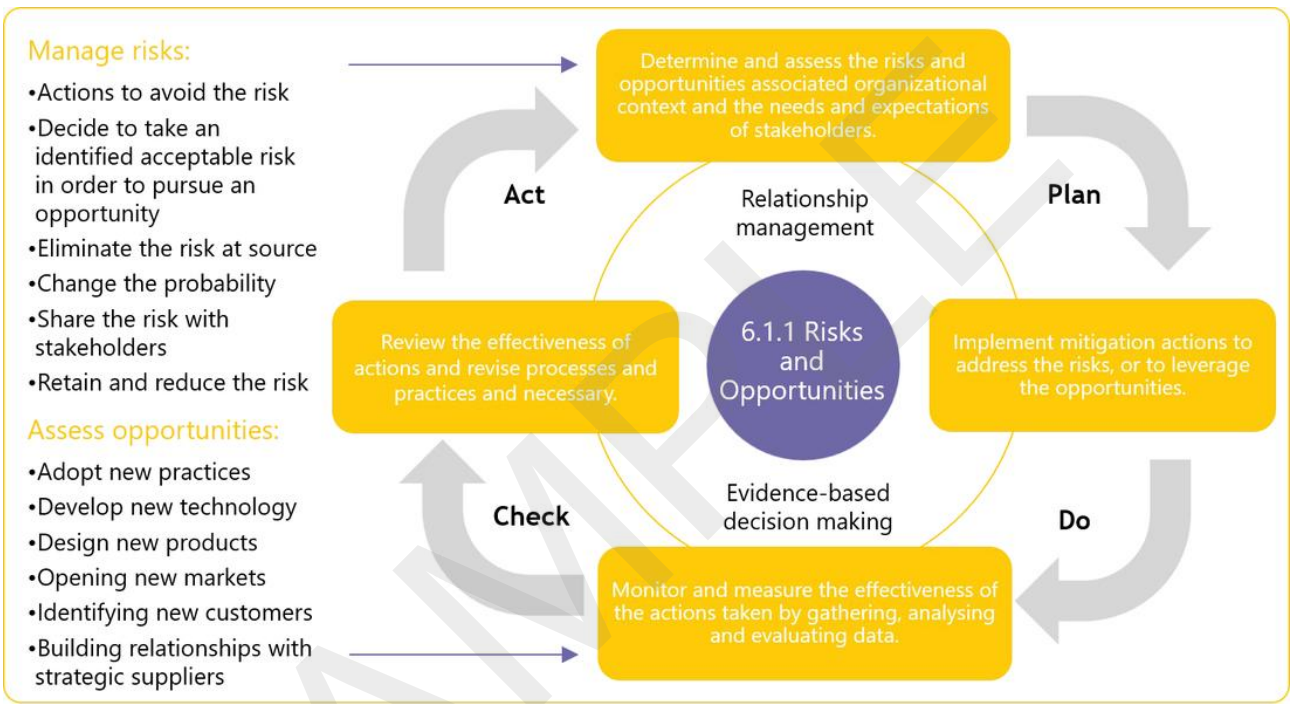
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6 Planning

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 Determining 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;
3. Reviewing information and results from audits and risk and opportunity management activities.

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Metrics	Definition
Nonconformity processing time	Average time to close all related actions after the opening date (measured over x rolling months)
First pass yield	The ratio of "passed" tests over the total number of tests in the last period
Complaint processing time	Average time to close all related actions after the opening date (measured over x rolling months)
Rate of the total cost of non-quality	A sum of all costs related to scrap, rework and repair, modifications, penalties, and extra warranty costs in relation to sales revenue
Claim and warranty costs	Total costs of claims and warranty in relation to sales revenue
Nonconformance costs before delivery	Nonconformance costs (e.g., all kinds of unplanned costs) before delivery in relation to the revenue of the product

Supporting documentation:

Doc No.	Title & Description
P0620-01	Quality Objectives Procedure

6.2.2 Planning to Achieve Objectives

Top Management is responsible for developing the programme of objectives and targets for the whole organization. The Quality manager is responsible for monitoring progress against our targets and objectives 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

Whenever management system changes are planned, Top management ensures that all personnel are made aware of any changes affecting their process and that subsequent monitoring is undertaken to ensure that quality management system changes are effectively implemented and do not adversely impact other processes.

To ensure that changes are implemented effectively and achieve their intended results, each change is planned considering: the purpose of the change and its potential consequences; the potential impact on the integrity of the quality management system; the availability of resources and information; the allocation or reallocation of responsibilities and authorities; how the change will be communicated; how the effectiveness

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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 *Supplier Evaluation Procedure*. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

Supporting documentation:

Doc No.	Title & Description
P0840-01	Supplier Evaluation Procedure

8.4.2 Purchasing Controls

Your organization ensures that externally provided processes, products, and services do not adversely affect our ability to deliver conforming products to our customers consistently. 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
90% or more	Systems are effective; start doing business with this supplier	No change in status; systems are effective; continue business with this supplier
75% to 89.9 %	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% to 74.9 %	Supplier may implement corrective actions and request re-audit	Request immediate corrective action and request re-audit; temporarily stop using until issues are fixed
Below 60%	There are severe problems and/or defects that could impact our business; reject the supplier	There are severe 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 product's effect on the subsequent realization of the end product.

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The amount and nature of inspection and test are based on the importance of the product characteristic, the process control exercised, and the specified requirements. All inspection and test activities are carried out by competent, authorized employees. Your organization uses the following methods to ensure product acceptance.

1. **Incoming inspection** - Incoming material is withheld pending completion of required inspection or receipt of objective evidence of conformance from the supplier;
2. **First-article inspection and testing** – Typically, the first produced unit that both the customer and supplier agree to use as the required baseline 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 available 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.

The *Nonconforming Outputs Procedure* defines the responsibilities, authorities, and methods used for the identification, segregation, review, and disposition of defective products, as well as the implementation of corrective action to prevent the recurrence of the nonconformance and action appropriate to the effect, or potential effects, of the nonconformance when a defective product is detected after delivery, or use has started.

Records clearly identifying the product, the nature and extent of nonconformance, the approved disposition, and corrective action taken are available as documented information in accordance with Section 7.5.

Disposition of Use as Is or Repair is only used after approval by an authorized representative of the organization responsible for the design.

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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 9000:2026. 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 9000:2026. 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 9000:2026. 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 9000:2026 or recording good practices. (3.10) Note 2 ISO 19011:2026. 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 them 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 a 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, methods, responsibilities, planning requirements, reporting, 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, ensuring it is relevant, risk-focused, and capable of evaluating operational, technological, and information security risks when planning and conducting internal audits.

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 plan defines the objectives, criteria, and scope of each audit, together with its frequency and methods. The selection of trained auditors and their subsequent impartial conduct ensure objectivity throughout the audit process and that:

1. The results of each are reported to the Quality Manager;
2. 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.

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.

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