Contents

Chapter 1

ISO 9001 Quality Management System Handbook - Metadata

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1.1 Handbook Information

Handbook Title: ISO 9001:2015 Quality Management System Handbook
Organization: {{ meta.organization }}
Author: Andreas Huemmer [andreas.huemmer@adminsend.de]
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1.2 Document Purpose

This handbook documents the organization's Quality Management System (QMS) in accordance with ISO 9001:2015. It describes the structure, processes, responsibilities, and procedures for ensuring the quality of products and services.

1.3 Scope

The QMS applies to: - {{ meta.qms_scope }}

1.4 Normative References

- ISO 9001:2015 - Quality management systems - Requirements
- ISO 9000:2015 - Quality management systems - Fundamentals and vocabulary
- ISO 9004:2018 - Quality management - Quality of an organization - Guidance to achieve sustained success

1.5 Change History

Version	Date	Author	Change
{{ meta.version }}	{{ meta.date }}	Andreas Huemmer [andreas.huemmer@adminsend.de]	Initial version

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Chapter 2

Understanding the Organization and its Context

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2.1 Purpose

This document describes the analysis of the organizational context according to ISO 9001:2015 Clause 4.1. It identifies internal and external issues that are relevant to the organization's purpose and strategic direction and that affect its ability to achieve the intended results of the quality management system.

2.2 Scope

This context analysis applies to: - **Organization:** {{ meta.organization }} - **Locations:** [TODO: List locations] - **Business units:** [TODO: List business units]

2.3 External Issues

2.3.1 Legal and Regulatory Environment

Issue	Description	Impact on QMS	Relevance
[TODO: Legal requirements]	[TODO: Description]	[TODO: Impact]	High/Medium/Low

Issue	Description	Impact on QMS	Relevance
[TODO: Industry regulations]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: Certification requirements]	[TODO: Description]	[TODO: Impact]	High/Medium/Low

2.3.2 Market and Competition

Issue	Description	Impact on QMS	Relevance
[TODO: Market trends]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: Competitive situation]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: Customer expectations]	[TODO: Description]	[TODO: Impact]	High/Medium/Low

2.3.3 Technological Environment

Issue	Description	Impact on QMS	Relevance
[TODO: Technological developments]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: Digitalization]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: Industry 4.0]	[TODO: Description]	[TODO: Impact]	High/Medium/Low

2.3.4 Economic Environment

Issue	Description	Impact on QMS	Relevance
[TODO: Economic conditions]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: Supply chain risks]	[TODO: Description]	[TODO: Impact]	High/Medium/Low

Issue	Description	Impact on QMS	Relevance
[TODO: Resource availability]	[TODO: Description]	[TODO: Impact]	High/Medium/Low

2.3.5 Social and Cultural Environment

Issue	Description	Impact on QMS	Relevance
[TODO: Social trends]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: Sustainability expectations]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: Labor availability]	[TODO: Description]	[TODO: Impact]	High/Medium/Low

2.4 Internal Issues

2.4.1 Organizational Structure and Governance

Issue	Description	Impact on QMS	Relevance
[TODO: Organizational structure]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: Leadership structure]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: Decision-making processes]	[TODO: Description]	[TODO: Impact]	High/Medium/Low

2.4.2 Resources and Capabilities

Issue	Description	Impact on QMS	Relevance
[TODO: Human resources]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: Technical resources]	[TODO: Description]	[TODO: Impact]	High/Medium/Low

Issue	Description	Impact on QMS	Relevance
[TODO: Financial resources]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: Knowledge and competencies]	[TODO: Description]	[TODO: Impact]	High/Medium/Low

2.4.3 Processes and Systems

Issue	Description	Impact on QMS	Relevance
[TODO: Business processes]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: IT systems]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: Quality management system]	[TODO: Description]	[TODO: Impact]	High/Medium/Low

2.4.4 Culture and Values

Issue	Description	Impact on QMS	Relevance
[TODO: Corporate culture]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: Quality culture]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: Corporate values]	[TODO: Description]	[TODO: Impact]	High/Medium/Low

2.4.5 Performance and Results

Issue	Description	Impact on QMS	Relevance
[TODO: Current performance]	[TODO: Description]	[TODO: Impact]	High/Medium/Low

Issue	Description	Impact on QMS	Relevance
[TODO: Customer satisfaction]	[TODO: Description]	[TODO: Impact]	High/Medium/Low
[TODO: Quality metrics]	[TODO: Description]	[TODO: Impact]	High/Medium/Low

2.5 Monitoring and Review

2.5.1 Review Frequency

The context analysis is reviewed: - **Regularly:** [TODO: e.g., annually, semi-annually] - **As needed:** When significant changes occur in internal or external context - **During management review:** According to Clause 9.3

2.5.2 Responsibilities

- **Responsible for review:** [TODO: Role/Person]
- **Approval:** [TODO: Role/Person]
- **Documentation:** [TODO: Role/Person]

2.5.3 Documentation of Changes

Significant changes in context are documented and their impact on the QMS is assessed.

2.6 Linkage to Other QMS Elements

This context analysis forms the basis for: - **Interested parties (4.2):** Identification of relevant interested parties - **QMS scope (4.3):** Determination of scope - **Risks and opportunities (6.1):** Identification of risks and opportunities - **Strategic direction:** Alignment of QMS with business strategy

2.7 Appendices

- **Appendix A:** PESTEL Analysis (Political, Economic, Social, Technological, Environmental, Legal)
- **Appendix B:** SWOT Analysis (Strengths, Weaknesses, Opportunities, Threats)
- **Appendix C:** Stakeholder Mapping

Next Steps: 1. Identify all relevant external and internal issues 2. Assess the impact of each issue on the QMS 3. Prioritize issues by relevance 4. Link context analysis to risk and opportunity assessment 5. Review and update the analysis regularly

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Chapter 3

Understanding the Needs and Expectations of Interested Parties

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3.1 Purpose

This document identifies the interested parties relevant to the quality management system and their requirements according to ISO 9001:2015 Clause 4.2. It ensures that the organization understands the needs and expectations that have an impact on its ability to consistently provide products and services that meet customer requirements and applicable statutory and regulatory requirements.

3.2 Scope

This analysis applies to: - **Organization:** {{ meta.organization }} - **QMS Scope:** [TODO: QMS scope]

3.3 Identification of Interested Parties

3.3.1 External Interested Parties

Interested Party	Relevance to QMS	Requirements/Expectations	Influence	Priority
Customers	High	[TODO: Product quality, delivery, service]	High	Critical
Regulatory Authorities	High	[TODO: Compliance, certifications]	High	Critical

Interested Party	Relevance to QMS	Requirements/Expectations	Influence	Priority
Suppliers	Medium	[TODO: Partnership, payment terms]	Medium	Important
Certification Bodies	High	[TODO: ISO 9001 conformity]	High	Critical
Society/Public	Medium	[TODO: Sustainability, social responsibility]	Medium	Important
Competitors	Low	[TODO: Market standards]	Low	Normal
Industry Associations	Medium	[TODO: Best practices, standards]	Medium	Important
[TODO: Others]	[TODO]	[TODO]	[TODO]	[TODO]

3.3.2 Internal Interested Parties

Interested Party	Relevance to QMS	Requirements/Expectations	Influence	Priority
Top Management	High	[TODO: Business success, compliance]	High	Critical
Employees	High	[TODO: Working conditions, development]	High	Critical
Quality Management	High	[TODO: Resources, authority]	High	Critical
Production/Operations	High	[TODO: Process efficiency, resources]	High	Critical
Sales/Marketing	Medium	[TODO: Product quality, customer satisfaction]	Medium	Important
Purchasing	Medium	[TODO: Supplier quality]	Medium	Important
[TODO: Other departments]	[TODO]	[TODO]	[TODO]	[TODO]

3.4 Detailed Requirements Analysis

3.4.1 Customers

Identification: - [TODO: Describe customer segments]

Requirements and Expectations: 1. **Product Quality:** - [TODO: Specific quality requirements] - [TODO: Performance characteristics] - [TODO: Reliability]

2. **Delivery and Service:**
   - [TODO: Delivery times]
   - [TODO: Availability]
   - [TODO: After-sales service]
3. **Communication:**
   - [TODO: Information provision]
   - [TODO: Complaint handling]
   - [TODO: Transparency]

Monitoring Methods: - Customer satisfaction surveys - Complaint analysis - Regular customer meetings - [TODO: Other methods]

3.4.2 Regulatory Authorities and Certification Bodies

Identification: - [TODO: List relevant authorities] - [TODO: List certification bodies]

Requirements and Expectations: 1. **Legal Requirements:** - [TODO: Product safety] - [TODO: Environmental regulations] - [TODO: Occupational health and safety]

2. **Normative Requirements:**
    - ISO 9001:2015 conformity
    - [TODO: Industry-specific standards]
    - [TODO: Other certifications]

Monitoring Methods: - Compliance audits - Regulatory updates - Certification audits - [TODO: Other methods]

3.4.3 Suppliers and Partners

Identification: - [TODO: Critical suppliers] - [TODO: Strategic partners]

Requirements and Expectations: 1. **From Suppliers:** - [TODO: Quality of deliveries] - [TODO: Delivery reliability] - [TODO: Communication]

2. **To Suppliers:**
    - [TODO: Fair business practices]
    - [TODO: Long-term partnerships]
    - [TODO: Payment terms]

Monitoring Methods: - Supplier evaluations - Quality audits - Regular meetings - [TODO: Other methods]

3.4.4 Employees

Identification: - All employees of the organization

Requirements and Expectations: 1. **Working Conditions:** - [TODO: Safe work environment] - [TODO: Adequate resources] - [TODO: Work-life balance]

2. **Development:**
    - [TODO: Training]
    - [TODO: Career opportunities]
    - [TODO: Competence development]
3. **Communication:**
    - [TODO: Transparent information]
    - [TODO: Involvement in decisions]
    - [TODO: Feedback opportunities]

Monitoring Methods: - Employee surveys - Employee interviews - Turnover rate - [TODO: Other methods]

3.5 Prioritization and Assessment

3.5.1 Assessment Criteria

Interested parties are assessed based on: 1. **Influence:** How strongly can the party influence the QMS? 2. **Dependency:** How dependent is the organization on this party? 3. **Impact:** What impact do the requirements have on the QMS? 4. **Urgency:** How urgently must the requirements be met?

3.5.2 Prioritization Matrix

Priority	Criteria	Actions
Critical	High influence + High dependency	Intensive monitoring, proactive management
Important	Medium influence or medium dependency	Regular monitoring, reactive management
Normal	Low influence + Low dependency	Periodic review

3.6 Monitoring and Review

3.6.1 Review Frequency

The interested parties analysis is reviewed: - **Regularly:** [TODO: e.g., annually] - **As needed:** When significant changes occur - **During management review:** According to Clause 9.3

3.6.2 Responsibilities

- **Responsible for review:** [TODO: Role/Person]
- **Approval:** [TODO: Role/Person]
- **Documentation:** [TODO: Role/Person]

3.6.3 Communication with Interested Parties

Interested Party	Communication Method	Frequency	Responsible
Customers	[TODO: Surveys, meetings]	[TODO]	[TODO]
Employees	[TODO: Meetings, newsletter]	[TODO]	[TODO]
Suppliers	[TODO: Audits, reviews]	[TODO]	[TODO]
[TODO]	[TODO]	[TODO]	[TODO]

3.7 Linkage to Other QMS Elements

This analysis forms the basis for: - **QMS Scope (4.3):** Consideration of requirements - **Quality Policy (5.2):** Alignment with stakeholder expectations - **Quality Objectives (6.2):** Derivation of objectives - **Risks and Opportunities (6.1):** Identification of risks - **Customer Satisfaction (9.1.2):** Monitoring of customer perception

3.8 Appendices

- **Appendix A:** Stakeholder Register (complete list)
- **Appendix B:** Requirements Matrix
- **Appendix C:** Communication Plan

Next Steps: 1. Identify all relevant interested parties 2. Analyze their requirements and expectations 3. Prioritize the interested parties 4. Define monitoring and communication methods 5. Review and update the analysis regularly

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Chapter 4

Determining the Scope of the QMS

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4.1 Purpose

This document defines the scope of the quality management system according to ISO 9001:2015 Clause 4.3. The scope establishes which products, services, processes, locations, and organizational units are covered by the QMS.

4.2 QMS Scope

4.2.1 Organizational Scope

Organization: - **Name:** {{ meta.organization }} - **Legal Form:** [TODO: e.g., LLC, Corporation] - **Headquarters:** [TODO: Address]

Included Locations: - [TODO: Location 1 - Address, Function] - [TODO: Location 2 - Address, Function] - [TODO: Additional locations]

Included Organizational Units: - [TODO: Department/Area 1] - [TODO: Department/Area 2] - [TODO: Additional areas]

Excluded Areas (if applicable): - [TODO: Area with justification] - [TODO: Additional exclusions]

4.2.2 Product and Service Scope

Included Products: - [TODO: Product category 1 - Description] - [TODO: Product category 2 - Description] - [TODO: Additional products]

Included Services: - [TODO: Service 1 - Description] - [TODO: Service 2 - Description] - [TODO: Additional services]

Excluded Products/Services (if applicable): - [TODO: Product/Service with justification]

4.2.3 Process Scope

Included Processes:

1. **Management Processes:**
   - [TODO: Strategic planning]
   - [TODO: Management review]
   - [TODO: Additional management processes]
2. **Core Processes:**
   - [TODO: Product development]
   - [TODO: Production/Service provision]
   - [TODO: Sales and marketing]
   - [TODO: Additional core processes]
3. **Support Processes:**
   - [TODO: Human resources management]
   - [TODO: IT management]
   - [TODO: Purchasing]
   - [TODO: Additional support processes]

Outsourced Processes: - [TODO: Process 1 - Service provider, Control method] - [TODO: Process 2 - Service provider, Control method]

4.3 Justification of Scope

4.3.1 Considered Factors

The scope was determined considering the following factors:

1. **External and Internal Issues (4.1):**
   - [TODO: Relevant context factors]
   - [TODO: Impact on scope]
2. **Requirements of Interested Parties (4.2):**
   - [TODO: Customer requirements]
   - [TODO: Regulatory requirements]
   - [TODO: Other stakeholder requirements]
3. **Products and Services:**
   - [TODO: Nature of products/services]
   - [TODO: Complexity]
   - [TODO: Customer groups]

4.3.2 Applicability of ISO 9001 Requirements

Fully Applicable Requirements: - All requirements of ISO 9001:2015 Clauses 4-10 are applicable

Non-Applicable Requirements (if applicable):

Clause	Requirement	Justification for Non-Applicability
[TODO: e.g., 8.3]	[TODO: Design and development]	[TODO: Justification, e.g., "No own product development, only production according to customer specifications"]

Note: Non-applicable requirements must not affect the organization's ability or responsibility to ensure conformity of products and services and enhancement of customer satisfaction.

4.4 Boundaries and Interfaces

4.4.1 Organizational Boundaries

Internal Interfaces: - [TODO: Interface between departments] - [TODO: Cross-location collaboration]

External Interfaces: - [TODO: Customers] - [TODO: Suppliers] - [TODO: External service providers] - [TODO: Regulatory authorities]

4.4.2 Process Boundaries

Process Inputs and Outputs: - [TODO: Main processes with inputs and outputs]

Outsourced Processes: - [TODO: Process, Service provider, Control mechanism]

4.5 Documentation of Scope

4.5.1 Availability

The QMS scope is available as: - Documented information in the QMS - [TODO: Quality manual] - [TODO: Intranet] - [TODO: Additional publication locations]

4.5.2 Communication

The scope is communicated to: - All employees - Customers (upon request) - Certification bodies - [TODO: Other interested parties]

4.6 Monitoring and Review

4.6.1 Review Frequency

The scope is reviewed: - **Regularly:** [TODO: e.g., annually] - **As needed:** When significant changes occur in: - Organizational structure - Product/service portfolio - Processes - External/internal context - **During management review:** According to Clause 9.3

4.6.2 Change Management

Changes to the scope require: 1. Assessment of impact on the QMS 2. Approval by [TODO: Role/Person] 3. Update of documented information 4. Communication to relevant interested parties 5. Notification of certification body if applicable

4.6.3 Responsibilities

- **Responsible for review:** [TODO: Quality management representative]
- **Approval:** [TODO: Top management]
- **Documentation:** [TODO: Role/Person]

4.7 Linkage to Other QMS Elements

The scope forms the basis for: - **Process map (4.4):** Definition of QMS processes - **Quality policy (5.2):** Alignment of policy - **Quality objectives (6.2):** Establishment of relevant objectives - **Resources (7.1):** Provision of necessary resources - **Certification:** Basis for certification audits

4.8 Appendices

- **Appendix A:** Detailed process map
- **Appendix B:** Location overview
- **Appendix C:** Product/service catalog

Next Steps: 1. Clearly define the organizational scope 2. List all included products and services 3. Identify all relevant processes 4. Justify any exclusions of ISO 9001 requirements 5. Communicate the scope to all relevant parties 6. Review the scope regularly

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Chapter 5

Quality Management System and its Processes

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5.1 Purpose

This document describes the quality management system and its processes according to ISO 9001:2015 Clause 4.4. It defines the required processes, their sequence, interaction, and the criteria for their effective operation and control.

5.2 QMS Process Approach

5.2.1 Process Model

The organization applies a process approach that includes the following elements: - Identification of processes required for the QMS - Determination of the sequence and interaction of these processes - Determination of criteria and methods for effective operation and control - Ensuring availability of resources and information - Monitoring, measurement, and analysis of processes - Implementation of actions to achieve objectives and continual improvement

5.2.2 Process Categories

1. Management Processes: - Strategic planning and objective setting - Management review - Internal audit - Continual improvement

2. Core Processes: - [TODO: Product development] - [TODO: Production/Service provision] - [TODO: Sales and customer management]

3. Support Processes: - Human resources management - Resource management - Document management - IT management

5.3 Process Descriptions

5.3.1 Process Template

For each process, the following elements are defined:

Element	Description
Process Name	[TODO: Name of the process]
Process Owner	[TODO: Responsible person/role]
Process Objective	[TODO: What should be achieved?]
Inputs	[TODO: What is needed?]
Outputs	[TODO: What is produced?]
Resources	[TODO: Personnel, equipment, infrastructure]
Methods	[TODO: How is the process performed?]
Monitoring	[TODO: KPIs, metrics]
Risks	[TODO: Identified risks]
Interfaces	[TODO: Upstream and downstream processes]

5.3.2 Management Processes

5.3.2.1 Strategic Planning

- **Process Owner:** [TODO: Top management]
- **Objective:** Establish strategic direction and quality objectives
- **Inputs:** Context analysis, stakeholder requirements, performance data
- **Outputs:** Quality policy, quality objectives, strategic plans
- **KPIs:** [TODO: e.g., objective achievement rate]

5.3.2.2 Management Review

- **Process Owner:** [TODO: Top management]
- **Objective:** Assess QMS effectiveness and suitability
- **Inputs:** Audit results, performance data, customer feedback
- **Outputs:** Management review report, improvement actions
- **KPIs:** [TODO: e.g., number of improvement actions]

5.3.2.3 Internal Audit

- **Process Owner:** [TODO: Quality management representative]
- **Objective:** Verify QMS conformity and effectiveness
- **Inputs:** Audit program, process documentation
- **Outputs:** Audit reports, nonconformities, improvement opportunities
- **KPIs:** [TODO: e.g., number of audits, nonconformities]

5.3.3 Core Processes

5.3.3.1 [TODO: Core Process 1 - e.g., Product Development]

- **Process Owner:** [TODO: Role/Person]
- **Objective:** [TODO: Process objective]
- **Inputs:** [TODO: Customer requirements, specifications]
- **Outputs:** [TODO: Product design, specifications]
- **KPIs:** [TODO: e.g., time-to-market, development costs]

5.3.3.2 [TODO: Core Process 2 - e.g., Production]

- **Process Owner:** [TODO: Role/Person]
- **Objective:** [TODO: Process objective]
- **Inputs:** [TODO: Production plans, materials]
- **Outputs:** [TODO: Finished products]
- **KPIs:** [TODO: e.g., scrap rate, throughput time]

5.3.3.3 [TODO: Core Process 3 - e.g., Sales]

- **Process Owner:** [TODO: Role/Person]
- **Objective:** [TODO: Process objective]
- **Inputs:** [TODO: Customer inquiries, product information]
- **Outputs:** [TODO: Orders, customer satisfaction]
- **KPIs:** [TODO: e.g., order intake, customer satisfaction]

5.3.4 Support Processes

5.3.4.1 Human Resources Management

- **Process Owner:** [TODO: HR manager]
- **Objective:** Ensure competent and motivated employees
- **Inputs:** Personnel needs, competence requirements
- **Outputs:** Qualified employees, training records
- **KPIs:** [TODO: e.g., training rate, employee satisfaction]

5.3.4.2 Document Management

- **Process Owner:** [TODO: Quality management representative]
- **Objective:** Control of documented information
- **Inputs:** Documents, change requests
- **Outputs:** Controlled documents, records
- **KPIs:** [TODO: e.g., document currency]

5.4 Process Interactions

5.4.1 Process Map

[TODO: Insert process map here or refer to appendix]

The process map shows: - All QMS processes - Process sequence and hierarchy - Main interfaces between processes - Inputs and outputs - External interfaces (customers, suppliers)

5.4.2 Interface Matrix

From Process	To Process	Interface/Handover	Responsible
[TODO]	[TODO]	[TODO: Document/Information]	[TODO]
[TODO]	[TODO]	[TODO: Document/Information]	[TODO]

5.5 Process Control and Monitoring

5.5.1 Control Criteria

For each process, the following are defined: 1. **Process Objectives:** Measurable objectives for process performance 2. **KPIs:** Metrics for monitoring objective achievement 3. **Responsibilities:** Process owners and participants 4. **Resources:** Required resources 5. **Methods:** Work instructions, procedures 6. **Monitoring:** Measurement and monitoring methods

5.5.2 Process KPIs

Process	KPI	Target Value	Measurement Frequency	Responsible
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

5.5.3 Process Monitoring

Methods: - Regular process reviews - KPI monitoring - Internal audits - Customer feedback - Employee feedback

Frequency: - [TODO: e.g., monthly, quarterly]

5.6 Resources and Information

5.6.1 Required Resources

Personnel: - [TODO: Number and qualification]

Infrastructure: - [TODO: Buildings, equipment, IT systems]

Work Environment: - [TODO: Physical and social factors]

5.6.2 Documented Information

Required Documents: - Process descriptions - Work instructions - Forms and templates - [TODO: Additional documents]

Records: - Process performance data - Audit results - Nonconformities - [TODO: Additional records]

5.7 Outsourced Processes

5.7.1 Control of Outsourced Processes

Process	Service Provider	Control Type	Monitoring	Responsible
[TODO]	[TODO]	[TODO: Contract, audit, KPIs]	[TODO]	[TODO]

Control Methods: - Contract management - Supplier evaluation - Regular audits - KPI monitoring - [TODO: Additional methods]

5.8 Continual Improvement

5.8.1 Improvement Approaches

- Process optimization based on KPI analysis
- Implementation of corrective actions
- Best practice sharing
- Lean/Six Sigma methods
- [TODO: Additional approaches]

5.8.2 Change Management

Process changes are controlled through: 1. Assessment of planned change 2. Approval by process owner 3. Update of documentation 4. Training of participants 5. Monitoring of effectiveness

5.9 Appendices

- **Appendix A:** Detailed process map
- **Appendix B:** Process descriptions (all processes)
- **Appendix C:** Interface matrix
- **Appendix D:** KPI dashboard

Next Steps: 1. Identify all QMS processes 2. Create process descriptions for each process 3. Define process interactions and interfaces 4. Establish KPIs and monitoring methods 5. Provide resources and information 6. Implement continual improvement

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Chapter 6

Process Interaction and Process Map

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6.1 Purpose

This document visualizes the process map of the quality management system and describes the interactions between processes. It serves as an overview of the entire QMS and shows how individual processes work together to achieve the intended results.

6.2 Process Map

6.2.1 Overview

The process map is structured into three main levels:

```
                    MANAGEMENT PROCESSES
  Strategic Planning | Management Review | Internal Audit

                              ↓

                      CORE PROCESSES
  [TODO: Process 1] → [TODO: Process 2] → [TODO: Process 3]

                              ↑

                  SUPPORT PROCESSES
  HR | Resources | Documentation | IT | Purchasing
```

6.2.2 Detailed Process Map

[TODO: Insert detailed process map as diagram here]

Note: The process map should be saved as a diagram in the `diagrams/` folder and referenced here.

6.3 Process Interactions

6.3.1 Management Processes

6.3.1.1 Strategic Planning

Inputs from: - Context of organization (4.1) - Interested parties (4.2) - Performance data from all processes

Outputs to: - All processes: Quality policy, quality objectives - Management review: Strategic directives - Resource management: Resource requirements

6.3.1.2 Management Review

Inputs from: - Internal audit: Audit results - All processes: Performance data, KPIs - Customer satisfaction: Feedback data - Risk management: Risk assessments

Outputs to: - Strategic planning: Improvement needs - All processes: Management decisions - Resource management: Resource decisions

6.3.1.3 Internal Audit

Inputs from: - All processes: Process documentation - Management review: Audit program - Risk management: Risk areas

Outputs to: - Management review: Audit results - Affected processes: Nonconformities - Improvement process: Improvement opportunities

6.3.2 Core Processes

6.3.2.1 [TODO: Core Process 1 - e.g., Sales/Customer Management]

Inputs from: - Customers: Inquiries, requirements - Marketing: Market information - Product development: Product information

Outputs to: - [TODO: Core Process 2]: Orders, specifications - Customers: Offers, order confirmations - Customer satisfaction: Feedback requests

6.3.2.2 [TODO: Core Process 2 - e.g., Product Development]

Inputs from: - Sales: Customer requirements - Market research: Market trends - Quality management: Quality requirements

Outputs to: - [TODO: Core Process 3]: Product specifications - Purchasing: Material lists - Production: Manufacturing documentation

6.3.2.3 [TODO: Core Process 3 - e.g., Production/Service Provision]

Inputs from: - Product development: Specifications - Purchasing: Materials, components - Quality control: Test specifications

Outputs to: - Quality control: Products for testing - Shipping: Finished products - Warehouse: Inventory

6.3.2.4 [TODO: Core Process 4 - e.g., Quality Control]

Inputs from: - Production: Products for testing - Product development: Test specifications - Goods receipt: Incoming materials

Outputs to: - Production: Test results, releases - Shipping: Release for delivery - Quality management: Quality data

6.3.2.5 [TODO: Core Process 5 - e.g., Shipping/Delivery]

Inputs from: - Quality control: Released products - Sales: Delivery instructions - Warehouse: Available products

Outputs to: - Customers: Delivered products - Sales: Delivery confirmations - After-sales: Handover for support

6.3.3 Support Processes

6.3.3.1 Human Resources Management

Inputs from: - All processes: Personnel needs, competence requirements - Strategic planning: HR strategy

Outputs to: - All processes: Qualified personnel - Training management: Training needs

6.3.3.2 Resource Management

Inputs from: - All processes: Resource requirements - Strategic planning: Budget directives

Outputs to: - All processes: Infrastructure, equipment - Maintenance: Maintenance plans

6.3.3.3 Document Management

Inputs from: - All processes: Documents, change requests - Quality management: Documentation requirements

Outputs to: - All processes: Controlled documents - Internal audit: Documentation evidence

6.3.3.4 IT Management

Inputs from: - All processes: IT requirements - Strategic planning: IT strategy

Outputs to: - All processes: IT systems, support - Data security: Security measures

6.3.3.5 Purchasing

Inputs from: - Production: Material needs - Product development: Specifications - Quality management: Supplier requirements

Outputs to: - Production: Materials, components - Goods receipt: Deliveries - Supplier management: Supplier evaluations

6.4 Process Flow and Value Chain

6.4.1 Main Value Chain

```
Customer → Sales → [TODO: Development] → [TODO: Production] →
[TODO: Quality Control] → [TODO: Shipping] → Customer
```

6.4.2 Supporting Processes

All core processes are supported by: - Human resources management (Competent employees) - Resource management (Infrastructure, equipment) - Document management (Documented information) - IT management (IT systems) - Purchasing (Materials, services)

6.4.3 Controlling Processes

All processes are controlled by: - Strategic planning (Directives, objectives) - Management review (Decisions, resources) - Internal audit (Monitoring, improvement)

6.5 Interfaces to External Parties

6.5.1 Customers

Interfaces: - Inquiries and requirements → Sales - Feedback and complaints → Customer satisfaction - Delivered products ← Shipping - After-sales support ← Service

6.5.2 Suppliers

Interfaces: - Orders → Purchasing - Deliveries → Goods receipt - Quality data ← Quality control - Supplier evaluations ← Supplier management

6.5.3 Regulatory Authorities

Interfaces: - Compliance requirements → Quality management - Evidence and reports ← Quality management - Audits and inspections Quality management

6.5.4 Certification Bodies

Interfaces: - Certification audits Quality management - Certificates ← Certification body - Surveillance audits Quality management

6.6 Process Performance and Monitoring

6.6.1 Process KPI Overview

Process	Main KPI	Target Value	Measurement Frequency
[TODO: Process 1]	[TODO: KPI]	[TODO]	[TODO]
[TODO: Process 2]	[TODO: KPI]	[TODO]	[TODO]
[TODO: Process 3]	[TODO: KPI]	[TODO]	[TODO]

6.6.2 Overall System KPIs

Quality objectives at system level: 1. [TODO: e.g., Customer satisfaction > 90%] 2. [TODO: e.g., Scrap rate < 2%] 3. [TODO: e.g., On-time delivery > 95%] 4. [TODO: e.g., Complaint rate < 1%]

6.7 Risks and Opportunities in Process Interactions

6.7.1 Identified Interface Risks

Interface	Risk	Impact	Measure
[TODO: Process A → B]	[TODO: Risk]	[TODO]	[TODO]
[TODO: Process C → D]	[TODO: Risk]	[TODO]	[TODO]

6.7.2 Opportunities in Process Interactions

Interface	Opportunity	Potential	Measure
[TODO: Process A → B]	[TODO: Opportunity]	[TODO]	[TODO]
[TODO: Process C → D]	[TODO: Opportunity]	[TODO]	[TODO]

6.8 Maintenance and Updates

6.8.1 Responsibilities

- **Maintenance of process map:** [TODO: Quality management representative]
- **Update upon process changes:** [TODO: Process owners]
- **Approval:** [TODO: Top management]

6.8.2 Update Triggers

The process map is updated when: - New or changed processes - Changes in process interactions - Organizational changes - Results of management review - Audit findings

6.9 Appendices

- **Appendix A:** Detailed process map (diagram)

- **Appendix B:** Process interaction matrix
- **Appendix C:** SIPOC diagrams (Supplier-Input-Process-Output-Customer)
- **Appendix D:** Process flow diagrams

Next Steps: 1. Create a visual process map 2. Document all process interactions 3. Identify critical interfaces 4. Define interface responsibilities 5. Monitor effectiveness of process interactions 6. Update the process map regularly

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Chapter 7

Quality Policy

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Version: {{ meta.version }}
Status: Draft
Classification: Internal
Last Update: {{ meta.date }}

7.1 Purpose

This document establishes the Quality Policy for {{ meta.organization }} in accordance with ISO 9001:2015 Clause 5.2. The quality policy expresses top management's commitment to quality and provides the framework for establishing and reviewing quality objectives.

7.2 Quality Policy Statement

[TODO: Insert organization's quality policy statement here. The policy should be concise, clear, and reflect the organization's commitment to quality, customer satisfaction, and continual improvement.]

Example:

"At {{ meta.organization }}, we are committed to: - Delivering products and services that consistently meet customer requirements and applicable regulatory requirements - Enhancing customer satisfaction through effective application of our quality management system - Continually improving the effectiveness of our quality management system - Providing the necessary resources and competent personnel to achieve our quality objectives - Fostering a culture of quality awareness and accountability throughout the organization"

7.3 Alignment with Organizational Context

The quality policy is aligned with: - **Organizational purpose:** [TODO: Describe alignment with mission/vision] - **Strategic direction:** [TODO: Describe alignment with business strategy] - **Con-**

text analysis: [TODO: Reference key internal/external issues from Clause 4.1] - **Interested parties:** [TODO: Reference key stakeholder expectations from Clause 4.2]

7.4 Commitment to Requirements

The quality policy includes commitment to: - **Customer requirements:** Meeting specified customer requirements - **Regulatory requirements:** Compliance with applicable legal and regulatory requirements - **Statutory requirements:** Adherence to relevant statutory obligations - **Contractual requirements:** Fulfillment of contractual obligations

7.5 Commitment to Continual Improvement

The organization is committed to continual improvement of: - **QMS effectiveness:** Improving the effectiveness of the quality management system - **Processes:** Enhancing process performance and efficiency - **Products and services:** Improving product and service quality - **Customer satisfaction:** Increasing customer satisfaction levels

7.6 Framework for Quality Objectives

The quality policy provides the framework for establishing quality objectives by: - **Defining focus areas:** [TODO: List key focus areas, e.g., customer satisfaction, process efficiency, product quality] - **Setting direction:** Providing strategic direction for objective setting - **Enabling measurement:** Establishing basis for measurable objectives - **Supporting alignment:** Ensuring objectives align with policy commitments

7.7 Communication and Availability

7.7.1 Communication Methods

The quality policy is communicated through: - **Internal communication:** [TODO: e.g., intranet, employee handbook, training sessions, team meetings] - **New employee orientation:** Included in onboarding process - **Regular reminders:** [TODO: e.g., quarterly all-hands meetings, newsletters] - **Visual displays:** Posted in common areas and work locations

7.7.2 Availability

The quality policy is available: - **To employees:** Accessible to all personnel at all times - **To interested parties:** Available to relevant external parties upon request - **In documented form:** Maintained as documented information - **Location:** [TODO: Specify where policy is available, e.g., intranet, quality manual, notice boards]

7.8 Understanding and Application

7.8.1 Ensuring Understanding

The organization ensures that the quality policy is: - **Understood:** Personnel understand the meaning and implications of the policy - **Applied:** Personnel apply the policy in their daily work - **Relevant:** Personnel understand how the policy relates to their roles

7.8.2 Training and Awareness

- **Initial training:** Quality policy included in employee onboarding
- **Ongoing awareness:** Regular communication and reinforcement
- **Assessment:** Understanding verified through [TODO: e.g., surveys, interviews, audits]

7.9 Review and Maintenance

7.9.1 Review Frequency

The quality policy is reviewed: - **Regularly:** [TODO: e.g., annually, during management review] - **As needed:** When significant changes occur in organizational context - **During management review:** As part of Clause 9.3 management review

7.9.2 Review Criteria

The policy is reviewed for: - **Continuing suitability:** Remains appropriate for organizational purpose and context - **Adequacy:** Provides adequate framework for quality objectives - **Effectiveness:** Supports achievement of intended QMS results - **Alignment:** Continues to align with strategic direction

7.9.3 Approval and Authorization

- **Developed by:** [TODO: Role/Person]
- **Reviewed by:** [TODO: Role/Person]
- **Approved by:** Top Management
- **Approval date:** [TODO: Date]
- **Next review date:** [TODO: Date]

7.10 Linkage to Other QMS Elements

The quality policy supports: - **Quality objectives (6.2):** Provides framework for setting objectives - **Leadership and commitment (5.1):** Demonstrates top management commitment - **Organizational roles (5.3):** Guides role definition and responsibilities - **Communication (7.4):** Subject of internal and external communication - **Management review (9.3):** Reviewed for continuing suitability

7.11 Documentation

- **Document location:** [TODO: Specify location]
- **Document format:** [TODO: e.g., PDF, printed poster, intranet page]
- **Version control:** Maintained according to documented information control (Clause 7.5)
- **Distribution:** [TODO: Describe distribution method]

Next Steps: 1. Develop quality policy statement with top management 2. Ensure alignment with organizational context and strategy 3. Obtain top management approval 4. Communicate policy to

all personnel 5. Establish quality objectives based on policy framework 6. Schedule regular policy reviews

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Chapter 8

Leadership and Commitment

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8.1 Purpose

This document describes how top management demonstrates leadership and commitment with respect to the quality management system in accordance with ISO 9001:2015 Clause 5.1.

8.2 Top Management Definition

Top Management: [TODO: Define who constitutes top management in your organization, e.g., CEO, Managing Director, Executive Board]

Members: - [TODO: Name, Title] - [TODO: Name, Title] - [TODO: Name, Title]

8.3 Accountability for QMS Effectiveness

Top management demonstrates accountability for the effectiveness of the QMS by:

8.3.1 Taking Ownership

- **Personal involvement:** [TODO: Describe how top management is personally involved in QMS]
- **Decision-making authority:** Final authority for QMS-related decisions
- **Resource allocation:** Direct involvement in resource decisions
- **Performance review:** Regular review of QMS performance

8.3.2 Evidence of Accountability

- Management review meetings (Clause 9.3)
- Approval of quality policy and objectives
- Resource allocation decisions
- Strategic planning involvement
- [TODO: Add organization-specific evidence]

8.4 Ensuring Policy and Objectives

Top management ensures that:

8.4.1 Quality Policy (5.2)

- Quality policy is established
- Policy is appropriate to organizational purpose and context
- Policy provides framework for quality objectives
- Policy is communicated and understood

8.4.2 Quality Objectives (6.2)

- Quality objectives are established for relevant functions and levels
- Objectives are consistent with quality policy
- Objectives are measurable and monitored
- Objectives support achievement of intended results

8.5 Integration of QMS Requirements

Top management ensures QMS requirements are integrated into business processes by:

8.5.1 Process Integration

- **Strategic planning:** QMS considerations in strategic planning
- **Business processes:** Quality requirements embedded in operational processes
- **Performance management:** Quality metrics in performance evaluation
- **Decision-making:** Quality considerations in business decisions

8.5.2 Integration Methods

- [TODO: Describe specific integration methods, e.g., process mapping, procedure development, system integration]
- [TODO: Identify key business processes where QMS is integrated]
- [TODO: Document integration checkpoints and verification]

8.6 Promoting Process Approach and Risk-Based Thinking

8.6.1 Process Approach

Top management promotes the process approach by: - **Process identification:** Ensuring processes are identified and managed - **Process interactions:** Understanding and managing process interactions - **Process performance:** Monitoring and measuring process performance - **Process improvement:** Driving process improvement initiatives

Evidence: - Process maps and documentation - Process performance reviews - Process improvement projects - [TODO: Add organization-specific evidence]

8.6.2 Risk-Based Thinking

Top management promotes risk-based thinking by: - **Risk awareness:** Fostering risk awareness culture - **Risk assessment:** Ensuring risks and opportunities are identified - **Risk treatment:** Supporting risk mitigation actions - **Preventive approach:** Emphasizing prevention over correction

Evidence: - Risk assessments conducted - Risk treatment plans implemented - Preventive actions taken - [TODO: Add organization-specific evidence]

8.7 Ensuring Resource Availability

Top management ensures resources needed for the QMS are available:

8.7.1 Resource Types

- **Human resources:** Competent personnel (Clause 7.2)
- **Infrastructure:** Facilities, equipment, and technology (Clause 7.1.3)
- **Process environment:** Suitable work environment (Clause 7.1.4)
- **Monitoring resources:** Measurement and monitoring resources (Clause 7.1.5)
- **Organizational knowledge:** Knowledge management (Clause 7.1.6)

8.7.2 Resource Allocation Process

- **Budget planning:** QMS resources included in budget
- **Resource requests:** Process for requesting QMS resources
- **Approval authority:** [TODO: Define approval authority for resources]
- **Resource review:** Regular review of resource adequacy

Evidence: - Budget allocations - Resource approval records - Training records - Equipment purchases - [TODO: Add organization-specific evidence]

8.8 Communicating Importance of QMS

Top management communicates the importance of effective quality management and conforming to QMS requirements by:

8.8.1 Communication Methods

- **Leadership messages:** [TODO: e.g., town halls, newsletters, emails]
- **Management meetings:** Regular communication in management meetings
- **Performance reviews:** Discussing quality in performance evaluations
- **Recognition programs:** Recognizing quality achievements
- **Personal example:** Leading by example in quality matters

8.8.2 Communication Frequency

- **Regular:** [TODO: Define frequency, e.g., quarterly, monthly]
- **Ad-hoc:** As needed for specific quality issues or achievements
- **Formal:** Through documented communications
- **Informal:** Through daily interactions and visibility

8.8.3 Communication Content

- Importance of meeting customer requirements
- Importance of meeting regulatory requirements
- Importance of QMS effectiveness
- Quality achievements and successes
- Quality challenges and improvement needs

8.9 Ensuring Intended Results

Top management ensures the QMS achieves its intended results by:

8.9.1 Intended Results Definition

- **Customer satisfaction:** [TODO: Define target satisfaction levels]
- **Product/service conformity:** [TODO: Define conformity targets]
- **Process performance:** [TODO: Define process performance targets]
- **Continual improvement:** [TODO: Define improvement targets]

8.9.2 Monitoring and Measurement

- Regular review of QMS performance indicators
- Analysis of customer feedback and satisfaction
- Review of nonconformities and corrective actions
- Assessment of improvement initiatives

8.9.3 Corrective Actions

- Taking action when intended results are not achieved
- Allocating resources to address performance gaps
- Adjusting strategy and objectives as needed

8.10 Engaging, Directing, and Supporting Persons

Top management engages, directs, and supports persons to contribute to QMS effectiveness by:

8.10.1 Engagement

- **Involvement:** Involving personnel in quality initiatives
- **Empowerment:** Empowering personnel to make quality decisions
- **Recognition:** Recognizing quality contributions
- **Feedback:** Seeking and acting on personnel feedback

8.10.2 Direction

- **Clear expectations:** Communicating quality expectations
- **Role clarity:** Ensuring clear roles and responsibilities
- **Guidance:** Providing guidance on quality matters
- **Priorities:** Setting quality priorities

8.10.3 Support

- **Resources:** Providing necessary resources
- **Training:** Ensuring competence through training
- **Tools:** Providing appropriate tools and systems
- **Removal of barriers:** Removing obstacles to quality

8.11 Promoting Improvement

Top management promotes improvement by:

8.11.1 Improvement Culture

- **Encouraging innovation:** Supporting new ideas and approaches
- **Learning from mistakes:** Treating failures as learning opportunities
- **Continuous improvement:** Emphasizing ongoing improvement
- **Benchmarking:** Encouraging comparison with best practices

8.11.2 Improvement Initiatives

- **Improvement projects:** Supporting improvement projects
- **Suggestion programs:** Implementing employee suggestion systems
- **Lessons learned:** Capturing and sharing lessons learned
- **Best practices:** Identifying and replicating best practices

8.11.3 Improvement Resources

- Allocating time for improvement activities
- Providing training on improvement methods
- Supporting improvement teams
- Recognizing improvement achievements

8.12 Supporting Other Management Roles

Top management supports other relevant management roles by:

8.12.1 Role Support

- **Authority:** Delegating appropriate authority
- **Resources:** Providing necessary resources
- **Guidance:** Offering guidance and direction
- **Backing:** Supporting management decisions

8.12.2 Specific Roles

- **Quality Manager:** [TODO: Describe support provided]
- **Process Owners:** [TODO: Describe support provided]
- **Department Managers:** [TODO: Describe support provided]
- **Project Managers:** [TODO: Describe support provided]

8.12.3 Collaboration

- Regular management meetings
- Cross-functional collaboration
- Shared objectives and accountability
- Open communication channels

8.13 Customer Focus (5.1.2)

Top management demonstrates leadership and commitment with respect to customer focus by ensuring:

8.13.1 Customer Requirements

- Customer and applicable statutory/regulatory requirements are determined, understood, and consistently met
- Risks and opportunities affecting product/service conformity and customer satisfaction are determined and addressed
- Focus on enhancing customer satisfaction is maintained

8.13.2 Customer Focus Activities

- **Customer engagement:** [TODO: Describe customer engagement activities]
- **Requirement analysis:** [TODO: Describe requirement determination process]
- **Risk assessment:** [TODO: Describe customer-related risk assessment]
- **Satisfaction monitoring:** [TODO: Describe satisfaction monitoring methods]

8.14 Evidence and Documentation

8.14.1 Leadership Evidence

- Management review records
- Resource allocation decisions
- Communication records
- Performance review records

- Strategic planning documents
- Quality policy and objectives approval
- [TODO: Add organization-specific evidence]

8.14.2 Documentation Location

- **Management review minutes:** [TODO: Location]
- **Communication records:** [TODO: Location]
- **Resource decisions:** [TODO: Location]
- **Performance data:** [TODO: Location]

8.15 Review and Improvement

8.15.1 Effectiveness Review

- Leadership effectiveness reviewed during management review
- Feedback from personnel on leadership support
- Assessment of QMS performance as indicator of leadership effectiveness
- [TODO: Define specific review methods]

8.15.2 Improvement Actions

- Actions taken to improve leadership effectiveness
- Changes to leadership practices based on feedback
- Enhanced communication or support mechanisms
- [TODO: Document specific improvement actions]

Next Steps: 1. Define top management composition 2. Document specific leadership activities and evidence 3. Establish communication methods for QMS importance 4. Define resource allocation process 5. Implement engagement and support mechanisms 6. Review leadership effectiveness regularly

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Chapter 9

Organizational Roles, Responsibilities, and Authorities

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9.1 Purpose

This document defines the organizational roles, responsibilities, and authorities relevant to the quality management system in accordance with ISO 9001:2015 Clause 5.3.

9.2 Organizational Structure

9.2.1 Organization Chart

[TODO: Insert or reference organizational chart showing QMS-relevant roles and reporting relationships]

9.2.2 QMS Governance Structure

[TODO: Describe QMS governance structure, including quality committees, steering groups, or other governance bodies]

9.3 Top Management Roles

9.3.1 Chief Executive Officer / Managing Director

Role Holder: [TODO: Name]

Responsibilities: - Overall accountability for QMS effectiveness - Approval of quality policy and objectives - Ensuring QMS integration into business processes - Allocation of resources for QMS - Leadership and commitment to QMS (Clause 5.1) - Chairing management review meetings (Clause 9.3)

Authorities: - Final decision-making authority for QMS matters - Authority to allocate resources - Authority to approve policies and strategic objectives - Authority to make organizational changes

9.3.2 [TODO: Other Top Management Roles]

Role Holder: [TODO: Name]

Responsibilities: - [TODO: Define responsibilities]

Authorities: - [TODO: Define authorities]

9.4 Quality Management Roles

9.4.1 Quality Manager / Management Representative

Role Holder: [TODO: Name]

Responsibilities: - Ensuring QMS conforms to ISO 9001 requirements - Ensuring processes deliver intended outputs - Reporting on QMS performance to top management - Promoting awareness of customer requirements - Ensuring integrity of QMS during changes - Coordinating internal audits - Managing corrective and preventive actions - Maintaining QMS documentation - Liaison with certification body

Authorities: - Authority to stop nonconforming processes - Authority to initiate corrective actions - Authority to access all areas and records for audit purposes - Authority to represent organization to certification body - Authority to approve QMS documentation

Reporting: Reports to [TODO: Position]

9.4.2 Quality Assurance Specialist(s)

Role Holder(s): [TODO: Name(s)]

Responsibilities: - Conducting internal audits - Monitoring process performance - Analyzing quality data and trends - Supporting corrective action implementation - Maintaining quality records - Training personnel on QMS requirements - Document control and management

Authorities: - Authority to audit all processes - Authority to request information and records - Authority to recommend corrective actions - Authority to approve controlled documents

Reporting: Reports to [TODO: Position]

9.5 Process Owner Roles

9.5.1 [TODO: Process Name] Process Owner

Role Holder: [TODO: Name]

Responsibilities: - Ensuring process achieves intended results - Monitoring process performance indicators - Identifying and implementing process improvements - Managing process resources - Ensuring process documentation is current - Addressing process nonconformities - Reporting process performance

Authorities: - Authority to make process changes within defined limits - Authority to allocate process resources - Authority to stop process if quality is at risk - Authority to request support from other functions

Reporting: Reports to [TODO: Position]

Key Processes: [TODO: List all key processes and assign process owners for each] - Sales and customer relationship management - Design and development - Purchasing and supplier management - Production/service delivery - Monitoring and measurement - Etc.

9.6 Operational Roles

9.6.1 Production Manager / Operations Manager

Role Holder: [TODO: Name]

Responsibilities: - Ensuring production/operations meet quality requirements - Managing operational resources - Implementing operational controls - Monitoring operational performance - Addressing operational nonconformities - Ensuring competence of operational personnel - Maintaining operational records

Authorities: - Authority to stop production for quality issues - Authority to allocate operational resources - Authority to approve operational procedures - Authority to make operational decisions

Reporting: Reports to [TODO: Position]

9.6.2 Department Managers

Role Holders: [TODO: Names and departments]

Responsibilities: - Ensuring departmental compliance with QMS requirements - Managing departmental resources - Monitoring departmental performance - Implementing corrective actions in department - Ensuring personnel competence - Maintaining departmental records

Authorities: - Authority to manage departmental operations - Authority to allocate departmental resources - Authority to approve departmental procedures - Authority to make departmental decisions

Reporting: Reports to [TODO: Position]

9.6.3 Team Leaders / Supervisors

Role Holders: [TODO: Names and teams]

Responsibilities: - Ensuring team compliance with work instructions - Monitoring team performance - Training and coaching team members - Reporting quality issues - Implementing corrective actions at team level - Maintaining team records

Authorities: - Authority to assign work to team members - Authority to stop work for quality issues - Authority to request support or resources - Authority to approve team-level decisions

Reporting: Reports to [TODO: Position]

9.7 Support Function Roles

9.7.1 Human Resources Manager

Role Holder: [TODO: Name]

Responsibilities: - Ensuring personnel competence (Clause 7.2) - Managing training and development programs - Maintaining competence records - Supporting awareness programs - Managing performance evaluation process

Authorities: - Authority to approve training programs - Authority to verify competence - Authority to manage HR processes

Reporting: Reports to [TODO: Position]

9.7.2 Maintenance Manager

Role Holder: [TODO: Name]

Responsibilities: - Ensuring infrastructure is maintained (Clause 7.1.3) - Managing maintenance resources - Implementing preventive maintenance - Ensuring measurement equipment calibration (Clause 7.1.5) - Maintaining maintenance records

Authorities: - Authority to schedule maintenance - Authority to allocate maintenance resources - Authority to stop equipment for maintenance

Reporting: Reports to [TODO: Position]

9.7.3 IT Manager

Role Holder: [TODO: Name]

Responsibilities: - Managing IT infrastructure supporting QMS - Ensuring data integrity and security - Managing QMS software and systems - Supporting process automation - Maintaining IT documentation

Authorities: - Authority to manage IT systems - Authority to implement IT changes - Authority to allocate IT resources

Reporting: Reports to [TODO: Position]

9.7.4 Purchasing Manager

Role Holder: [TODO: Name]

Responsibilities: - Ensuring purchased products/services meet requirements (Clause 8.4) - Managing supplier evaluation and selection - Monitoring supplier performance - Managing purchasing processes - Maintaining supplier records

Authorities: - Authority to select and approve suppliers - Authority to place purchase orders - Authority to reject nonconforming supplies

Reporting: Reports to [TODO: Position]

9.8 Customer-Facing Roles

9.8.1 Sales Manager

Role Holder: [TODO: Name]

Responsibilities: - Determining customer requirements (Clause 8.2.2) - Managing customer communication (Clause 8.2.1) - Reviewing contracts and orders (Clause 8.2.3) - Monitoring customer satisfaction (Clause 9.1.2) - Managing customer complaints

Authorities: - Authority to accept customer orders - Authority to negotiate with customers - Authority to approve contract changes

Reporting: Reports to [TODO: Position]

9.8.2 Customer Service Manager

Role Holder: [TODO: Name]

Responsibilities: - Managing customer inquiries and feedback - Handling customer complaints - Monitoring customer satisfaction - Coordinating with other departments on customer issues - Maintaining customer communication records

Authorities: - Authority to resolve customer issues - Authority to approve customer accommodations - Authority to escalate major issues

Reporting: Reports to [TODO: Position]

9.9 Specific QMS Responsibilities

9.9.1 Ensuring QMS Conformity (5.3a)

Assigned to: Quality Manager

Responsibilities: - Monitoring QMS conformity to ISO 9001 requirements - Conducting gap analyses - Coordinating corrective actions for nonconformities - Reporting conformity status to top management

9.9.2 Ensuring Process Outputs (5.3b)

Assigned to: Process Owners

Responsibilities: - Monitoring process performance - Ensuring processes deliver intended outputs - Taking corrective action when outputs don't meet requirements - Reporting process performance

9.9.3 Reporting QMS Performance (5.3c)

Assigned to: Quality Manager

Responsibilities: - Collecting and analyzing QMS performance data - Preparing management review reports - Reporting on QMS effectiveness - Identifying improvement opportunities

9.9.4 Promoting Customer Focus (5.3d)

Assigned to: All Management

Responsibilities: - Ensuring customer requirements are understood - Promoting customer focus throughout organization - Monitoring customer satisfaction - Addressing customer concerns

9.9.5 Ensuring QMS Integrity During Changes (5.3e)

Assigned to: Quality Manager

Responsibilities: - Assessing impact of changes on QMS - Ensuring QMS integrity is maintained during changes - Coordinating change implementation - Updating QMS documentation for changes

9.10 RACI Matrix

[TODO: Create RACI matrix showing Responsible, Accountable, Consulted, Informed for key QMS activities]

Activity	Top Mgmt	Quality Mgr	Process Owner	Dept Mgr	Other
Quality Policy	A	R	C	I	I
Quality Objectives	A	R	R	C	I
Management Review	A/R	R	C	C	I
Internal Audit	A	R	C	C	I
Corrective Action	A	R	R	R	C
Document Control	A	R	C	C	I
[TODO: Add more activities]					

Legend: - R = Responsible (does the work) - A = Accountable (final authority) - C = Consulted (provides input) - I = Informed (kept informed)

9.11 Communication of Roles

9.11.1 Communication Methods

Roles, responsibilities, and authorities are communicated through: - **Job descriptions:** Formal job descriptions include QMS responsibilities - **Organizational charts:** Visual representation of reporting relationships - **Intranet:** Published on company intranet - **Training:** Included in employee onboarding and training - **Meetings:** Discussed in team and department meetings - **Performance reviews:** Reviewed during performance evaluations

9.11.2 Ensuring Understanding

Understanding of roles is ensured through: - **Acknowledgment:** Personnel acknowledge understanding of their roles - **Training:** Training provided on role-specific responsibilities - **Assess-**

ment: Understanding verified through [TODO: method] - **Feedback:** Regular feedback on role performance

9.12 Delegation and Substitution

9.12.1 Delegation Process

When role holders delegate responsibilities: - Delegation must be documented - Delegate must be competent - Authority must be clearly defined - Accountability remains with role holder

9.12.2 Substitution Arrangements

For key QMS roles, substitution arrangements are defined: - **Quality Manager substitute:** [TODO: Name/Position] - **Process Owner substitutes:** [TODO: Define for each process] - **Other key roles:** [TODO: Define substitutes]

9.13 Review and Updates

9.13.1 Review Frequency

Roles, responsibilities, and authorities are reviewed: - **Annually:** As part of management review - **When changes occur:** Organizational changes, process changes, role changes - **After audits:** Based on audit findings - **As needed:** When issues are identified

9.13.2 Update Process

Updates to roles are: - Proposed by [TODO: Role] - Reviewed by [TODO: Role] - Approved by Top Management - Communicated to affected personnel - Documented and version controlled

9.14 Documentation

- **Document location:** [TODO: Specify location]
- **Related documents:** Job descriptions, organizational charts, process documentation
- **Version control:** Maintained according to Clause 7.5
- **Distribution:** Available to all personnel

Next Steps: 1. Define all QMS-relevant roles in organization 2. Assign specific responsibilities and authorities to each role 3. Create RACI matrix for key QMS activities 4. Communicate roles to all personnel 5. Ensure understanding through training and acknowledgment 6. Review and update roles regularly

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Chapter 10

Management Review

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10.1 Purpose

This document defines the Management Review process for {{ meta.organization }} in accordance with ISO 9001:2015 Clause 9.3. Management review ensures the QMS remains suitable, adequate, effective, and aligned with the strategic direction of the organization.

10.2 Management Review Planning

10.2.1 Review Frequency

Management reviews are conducted: - **Regular schedule:** [TODO: e.g., quarterly, semi-annually, annually] - **Specific dates:** [TODO: Define scheduled review dates for current year] - **Ad-hoc reviews:** As needed when significant changes or issues occur

10.2.2 Review Participants

Required Participants: - Top Management (Chair) - Quality Manager - Process Owners - [TODO: Add other required participants]

Optional Participants (as needed): - Department Managers - Subject matter experts - External consultants - [TODO: Add other optional participants]

10.2.3 Meeting Logistics

- **Duration:** [TODO: e.g., 2-4 hours]
- **Location:** [TODO: e.g., conference room, virtual meeting]

- **Scheduling:** Scheduled [TODO: timeframe] in advance
- **Preparation:** Materials distributed [TODO: timeframe] before meeting

10.3 Management Review Inputs (9.3.2)

10.3.1 Status of Actions from Previous Reviews

Data Source: Previous management review minutes and action tracking

Content: - Status of action items from previous review - Completion of assigned actions - Effectiveness of completed actions - Outstanding actions and reasons for delays

Responsible: Quality Manager

10.3.2 Changes in External and Internal Issues

Data Source: Context analysis (Clause 4.1), interested parties analysis (Clause 4.2)

Content: - Changes in external issues (market, regulatory, technology, competition) - Changes in internal issues (resources, processes, structure, culture) - Impact of changes on QMS - Required QMS adaptations

Responsible: [TODO: Role]

10.3.3 Information on QMS Performance and Effectiveness

10.3.3.1 Customer Satisfaction (9.1.2)

Data Source: Customer satisfaction surveys, feedback, complaints

Content: - Customer satisfaction trends - Customer feedback analysis - Complaint statistics and trends - Customer retention rates - Net Promoter Score (if applicable)

Responsible: [TODO: Role]

10.3.3.2 Extent to Which Quality Objectives Have Been Met (6.2)

Data Source: Quality objectives tracking and measurement

Content: - Status of each quality objective - Achievement levels vs. targets - Trends over time - Reasons for deviations - Proposed adjustments

Responsible: Process Owners / Quality Manager

10.3.3.3 Process Performance and Product/Service Conformity

Data Source: Process monitoring data, product/service inspection results

Content: - Process performance indicators and trends - Process capability analysis - Product/service conformity rates - Defect rates and trends - First-pass yield - Rework and scrap rates

Responsible: Process Owners

10.3.3.4 Nonconformities and Corrective Actions (10.2)

Data Source: Nonconformity records, corrective action tracking

Content: - Number and types of nonconformities - Nonconformity trends - Status of corrective actions - Effectiveness of corrective actions - Recurring nonconformities - Root cause analysis results

Responsible: Quality Manager

10.3.3.5 Monitoring and Measurement Results (9.1)

Data Source: Monitoring and measurement data

Content: - Results of process monitoring - Results of product/service measurement - Measurement system performance - Calibration status - Monitoring effectiveness

Responsible: [TODO: Role]

10.3.3.6 Audit Results (9.2)

Data Source: Internal audit reports, external audit reports

Content: - Internal audit findings and trends - Audit nonconformities and observations - Status of audit corrective actions - External audit results (certification, customer, regulatory) - Audit program effectiveness

Responsible: Quality Manager

10.3.3.7 Performance of External Providers (8.4)

Data Source: Supplier performance data, supplier audits

Content: - Supplier performance metrics - Supplier quality issues - Supplier delivery performance - Supplier audit results - Changes in supplier base

Responsible: Purchasing Manager

10.3.4 Adequacy of Resources (7.1)

Data Source: Resource planning, budget data, competence records

Content: - Adequacy of human resources - Adequacy of infrastructure - Adequacy of process environment - Adequacy of monitoring resources - Adequacy of organizational knowledge - Resource gaps and needs

Responsible: [TODO: Role]

10.3.5 Effectiveness of Actions Taken to Address Risks and Opportunities (6.1)

Data Source: Risk register, risk treatment tracking

Content: - Status of risk treatment actions - Effectiveness of risk mitigation - New risks identified - Opportunities pursued - Changes in risk profile

Responsible: [TODO: Role]

10.3.6 Opportunities for Improvement (10.3)

Data Source: Improvement initiatives, suggestion programs, lessons learned

Content: - Improvement opportunities identified - Status of improvement initiatives - Results of improvement actions - Benchmarking results - Innovation proposals

Responsible: [TODO: Role]

10.4 Management Review Outputs (9.3.3)

Management review outputs must include decisions and actions related to:

10.4.1 Opportunities for Improvement

Decisions: - Approval of improvement initiatives - Prioritization of improvement opportunities - Resource allocation for improvements - Improvement targets and timelines

Actions: - [TODO: Document specific improvement actions decided] - Assigned to: [TODO: Role] - Due date: [TODO: Date]

10.4.2 Need for Changes to QMS

Decisions: - Changes to QMS scope - Changes to processes - Changes to documentation - Changes to resources

Actions: - [TODO: Document specific change actions decided] - Assigned to: [TODO: Role] - Due date: [TODO: Date]

10.4.3 Resource Needs

Decisions: - Additional resource requirements - Resource reallocation - Budget adjustments - Competence development needs

Actions: - [TODO: Document specific resource actions decided] - Assigned to: [TODO: Role] - Due date: [TODO: Date]

10.5 Management Review Process

10.5.1 Pre-Review Preparation

Timeline: [TODO: e.g., 2 weeks before review]

Activities: 1. Quality Manager collects input data from all sources 2. Quality Manager prepares management review report 3. Quality Manager distributes report to participants 4. Participants review materials and prepare comments 5. Quality Manager schedules meeting and confirms attendance

10.5.2 Review Meeting

Agenda: 1. Opening and review of previous action items 2. Review of management review inputs 3. Discussion of QMS performance and effectiveness 4. Identification of improvement opportunities

5. Decision-making on required actions 6. Assignment of responsibilities and deadlines 7. Closing and next steps

Facilitation: - Meeting chaired by Top Management - Quality Manager presents data and facilitates discussion - Participants provide input and recommendations - Decisions documented in real-time

10.5.3 Post-Review Actions

Timeline: [TODO: e.g., within 1 week after review]

Activities: 1. Quality Manager prepares management review minutes 2. Minutes distributed to participants for review 3. Top Management approves minutes 4. Action items communicated to responsible persons 5. Action tracking initiated 6. Follow-up scheduled

10.6 Documentation and Records

10.6.1 Management Review Minutes

Content: - Date, time, location, participants - Summary of inputs reviewed - Key discussions and decisions - Actions decided with assignments and deadlines - Signatures of Top Management and Quality Manager

Format: [TODO: Define format, e.g., template, structured document]

Storage: [TODO: Define storage location]

Retention: [TODO: Define retention period, e.g., 10 years]

10.6.2 Supporting Documentation

- Input data reports
- Presentations
- Analysis documents
- Action tracking logs

10.7 Action Tracking and Follow-Up

10.7.1 Action Item Management

Each action item includes: - **Action description:** Clear description of required action - **Assigned to:** Responsible person - **Due date:** Target completion date - **Status:** Not started / In progress / Completed - **Completion evidence:** Documentation of completion

10.7.2 Tracking Method

Actions tracked through: - [TODO: e.g., action tracking spreadsheet, project management tool, QMS software]

10.7.3 Follow-Up Process

- Quality Manager monitors action progress
- Reminders sent to responsible persons

- Status updates requested [TODO: frequency]
- Escalation to Top Management if actions delayed
- Completed actions verified before closing

10.8 Effectiveness Evaluation

10.8.1 Review Effectiveness Criteria

Management review effectiveness evaluated based on: - Timeliness of reviews - Quality of input data - Participation and engagement - Quality of decisions made - Completion of action items - Impact on QMS performance

10.8.2 Improvement of Review Process

The management review process itself is subject to continual improvement: - Feedback collected from participants - Review format and content adjusted as needed - Input data sources refined - Action tracking improved

10.9 Integration with Other Processes

Management review integrates with: - **Internal audit (9.2):** Audit results are key input - **Corrective action (10.2):** Actions may result from review - **Risk management (6.1):** Risk effectiveness reviewed - **Improvement (10.3):** Improvement opportunities identified - **Strategic planning:** QMS aligned with strategy

10.10 Management Review Schedule

10.10.1 Current Year Schedule

Review #	Planned Date	Status	Actual Date	Minutes Reference
Review 1	[TODO: Date]	[TODO: Planned/Completed]	[TODO: Date]	[TODO: Reference]
Review 2	[TODO: Date]	[TODO: Planned/Completed]	[TODO: Date]	[TODO: Reference]
Review 3	[TODO: Date]	[TODO: Planned/Completed]	[TODO: Date]	[TODO: Reference]
Review 4	[TODO: Date]	[TODO: Planned/Completed]	[TODO: Date]	[TODO: Reference]

10.10.2 Historical Reviews

Year	Number of Reviews	Key Outcomes
[TODO: Year]	[TODO: Number]	[TODO: Summary]
[TODO: Year]	[TODO: Number]	[TODO: Summary]

Next Steps: 1. Define management review schedule for current year 2. Identify all input data sources and responsible persons 3. Develop management review report template 4. Conduct first management review 5. Implement action tracking system 6. Review and improve management review process

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Chapter 11

Actions to Address Risks and Opportunities

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11.1 Purpose

This document defines the process for determining and addressing risks and opportunities that can affect the ability of the QMS to achieve its intended results, in accordance with ISO 9001:2015 Clause 6.1.

11.2 Risk Management Framework

11.2.1 Risk Management Approach

{{ meta.organization }} uses a systematic approach to identify, assess, and treat risks and opportunities related to the QMS.

Risk Management Methodology: [TODO: e.g., ISO 31000, FMEA, risk matrix]

Risk-Based Thinking: Integrated into all QMS processes and decision-making

11.2.2 Scope of Risk Assessment

Risk assessment covers: - **QMS processes:** Risks affecting process performance - **Products and services:** Risks affecting conformity and customer satisfaction - **External context:** Risks from external issues (Clause 4.1) - **Internal context:** Risks from internal issues (Clause 4.1) - **Interested parties:** Risks related to stakeholder requirements (Clause 4.2)

11.3 Risk and Opportunity Identification

11.3.1 Sources of Risks and Opportunities

Risks and opportunities are identified from: - Context analysis (Clause 4.1) - Interested parties requirements (Clause 4.2) - Process analysis - Customer feedback - Audit findings - Nonconformities and complaints - Market and technology changes - Regulatory changes - Performance data and trends

11.3.2 Risk Categories

Strategic Risks: - Market changes - Competitive threats - Regulatory changes - Technology disruption

Operational Risks: - Process failures - Resource constraints - Supplier issues - Equipment breakdowns

Compliance Risks: - Regulatory non-compliance - Customer requirement violations - Standard non-conformity

Reputational Risks: - Customer dissatisfaction - Quality failures - Negative publicity

11.3.3 Opportunity Categories

Improvement Opportunities: - Process optimization - Technology adoption - Innovation initiatives

Growth Opportunities: - New markets - New products/services - Customer expansion

Efficiency Opportunities: - Cost reduction - Waste elimination - Automation

11.4 Risk Assessment Process

11.4.1 Risk Identification Workshops

Frequency: [TODO: e.g., annually, semi-annually]

Participants: - Top Management - Quality Manager - Process Owners - Subject matter experts

Method: [TODO: e.g., brainstorming, SWOT analysis, PESTEL analysis]

11.4.2 Risk Analysis

Each identified risk is analyzed for:

Likelihood: Probability of occurrence - **High:** Likely to occur (>50% probability) - **Medium:** May occur (10-50% probability) - **Low:** Unlikely to occur (<10% probability)

Impact: Consequence if risk occurs - **High:** Severe impact on QMS objectives, customer satisfaction, or compliance - **Medium:** Moderate impact, manageable with effort - **Low:** Minor impact, easily managed

11.4.3 Risk Evaluation

Risk Level = Likelihood × Impact

Likelihood	Low Impact	Medium Impact	High Impact
High	Medium	High	Critical
Medium	Low	Medium	High
Low	Low	Low	Medium

Risk Priorities: - **Critical:** Immediate action required - **High:** Action required within [TODO: timeframe] - **Medium:** Action required within [TODO: timeframe] - **Low:** Monitor, action if needed

11.5 Risk Register

11.5.1 Risk Documentation

Each risk is documented with: - **Risk ID:** Unique identifier - **Risk description:** Clear description of the risk - **Risk category:** Strategic, operational, compliance, reputational - **Risk owner:** Person responsible for managing the risk - **Likelihood:** High / Medium / Low - **Impact:** High / Medium / Low - **Risk level:** Critical / High / Medium / Low - **Current controls:** Existing controls or mitigation measures - **Treatment plan:** Planned actions to address risk - **Status:** Open / In progress / Closed - **Review date:** Next review date

11.5.2 Risk Register Template

Risk ID	Description	Category	Owner	L	I	Level	Current Controls	Treatment Plan	Status	Review Date
R001	[TODO]	[TODO]	[TODO]	H/M/L	H/M/L	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]
R002	[TODO]	[TODO]	[TODO]	H/M/L	H/M/L	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

11.6 Opportunity Register

11.6.1 Opportunity Documentation

Each opportunity is documented with: - **Opportunity ID:** Unique identifier - **Opportunity description:** Clear description - **Opportunity category:** Improvement, growth, efficiency - **Opportunity owner:** Person responsible - **Potential benefit:** Expected benefit if pursued - **Feasibility:** High / Medium / Low - **Priority:** High / Medium / Low - **Action plan:** Planned actions to pursue opportunity - **Status:** Under evaluation / Approved / In progress / Realized / Rejected - **Review date:** Next review date

11.6.2 Opportunity Register Template

Opp ID	Description	Category	Owner	Benefit	Feasibility	Priority	Action Plan	Status	Review Date
O001	[TODO]	[TODO]	[TODO]	[TODO]	H/M/L	H/M/L	[TODO]	[TODO]	[TODO]
O002	[TODO]	[TODO]	[TODO]	[TODO]	H/M/L	H/M/L	[TODO]	[TODO]	[TODO]

11.7 Risk Treatment Options

11.7.1 Risk Treatment Strategies

Avoid: Eliminate the risk by not performing the activity - Example: Not entering a high-risk market

Reduce: Implement controls to reduce likelihood or impact - Example: Implementing quality controls, training, procedures

Transfer: Share the risk with another party - Example: Insurance, outsourcing, contracts

Accept: Accept the risk and monitor - Example: Low-level risks with acceptable consequences

11.7.2 Treatment Action Planning

For each risk requiring treatment: - **Treatment actions:** Specific actions to be taken - **Responsible person:** Who will implement actions - **Target date:** When actions will be completed - **Resources required:** Resources needed for implementation - **Success criteria:** How effectiveness will be measured

11.8 Integration into QMS Processes

11.8.1 Process-Level Risk Management

Each QMS process includes: - Identification of process-specific risks - Risk controls built into process design - Monitoring of risk indicators - Regular risk review

11.8.2 Risk Considerations in Planning

Risks and opportunities considered in: - **Quality objectives (6.2):** Objectives address key risks and opportunities - **Change planning (6.3):** Changes assessed for risk - **Resource planning (7.1):** Resources allocated based on risk - **Operational planning (8.1):** Operations designed to manage risk - **Improvement planning (10.3):** Improvements target risk reduction

11.9 Monitoring and Review

11.9.1 Risk Monitoring

Risks are monitored through: - **Key risk indicators:** Metrics that signal risk changes - **Regular reviews:** Scheduled risk register reviews - **Trigger events:** Events that require immediate risk reassessment - **Audit findings:** Internal and external audit results

11.9.2 Review Frequency

- **Ongoing:** Continuous monitoring of key risks
- **Quarterly:** Review of risk register
- **Annually:** Comprehensive risk assessment
- **As needed:** When significant changes occur

11.9.3 Review Responsibilities

- **Risk owners:** Monitor assigned risks
- **Quality Manager:** Coordinate risk review process
- **Top Management:** Review critical and high risks
- **Management review:** Risks reviewed in management review (Clause 9.3)

11.10 Effectiveness Evaluation

11.10.1 Treatment Effectiveness

Effectiveness of risk treatment actions evaluated by: - Achievement of risk reduction targets - Changes in risk likelihood or impact - Absence of risk materialization - Cost-benefit analysis of treatments

11.10.2 Continuous Improvement

Risk management process improved through: - Lessons learned from risk events - Feedback from risk owners - Benchmarking with best practices - Updates to risk methodology

11.11 Documentation and Records

11.11.1 Maintained Records

- Risk register (current and historical)
- Opportunity register
- Risk assessment reports
- Risk treatment plans
- Risk review meeting minutes
- Risk monitoring data

11.11.2 Document Control

- **Location:** [TODO: Specify location]
- **Access:** [TODO: Define access rights]
- **Retention:** [TODO: Define retention period]
- **Version control:** Maintained according to Clause 7.5

11.12 Training and Awareness

11.12.1 Risk Management Training

Personnel receive training on: - Risk-based thinking principles - Risk identification methods - Risk assessment process - Risk treatment responsibilities - Risk reporting procedures

11.12.2 Target Audience

- **All personnel:** Basic risk awareness
- **Management:** Risk assessment and treatment
- **Process owners:** Process-specific risk management
- **Quality team:** Detailed risk management methodology

Next Steps: 1. Conduct initial risk and opportunity assessment 2. Establish risk and opportunity registers 3. Assign risk owners and develop treatment plans 4. Integrate risk management into QMS processes 5. Implement risk monitoring and review process 6. Train personnel on risk-based thinking

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Chapter 12

Quality Objectives and Planning to Achieve Them

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12.1 Purpose

This document establishes quality objectives for {{ meta.organization }} and defines planning to achieve them, in accordance with ISO 9001:2015 Clause 6.2.

12.2 Quality Objectives Framework

12.2.1 Alignment with Quality Policy

Quality objectives are derived from and support the quality policy commitments: - [TODO: Link each objective to specific quality policy statement]

12.2.2 Alignment with Strategic Direction

Quality objectives support organizational strategy: - [TODO: Describe how objectives align with business strategy]

12.2.3 Consideration of Risks and Opportunities

Quality objectives address key risks and opportunities identified in Clause 6.1: - [TODO: Link objectives to specific risks and opportunities]

12.3 Organizational-Level Quality Objectives

12.3.1 Objective 1: [TODO: Customer Satisfaction]

Description: [TODO: e.g., Achieve and maintain customer satisfaction score of 4.5/5.0]

Measurable Target: [TODO: Specific numeric target]

Measurement Method: [TODO: e.g., Customer satisfaction survey, NPS]

Baseline: [TODO: Current performance level]

Target Date: [TODO: Achievement date]

Responsible: [TODO: Role/Person]

Resources Required: [TODO: Resources needed]

Monitoring Frequency: [TODO: e.g., Quarterly]

Status: [TODO: On track / At risk / Behind]

12.3.2 Objective 2: [TODO: Product/Service Quality]

Description: [TODO: e.g., Reduce nonconformity rate to $< 2\%$]

Measurable Target: [TODO: Specific numeric target]

Measurement Method: [TODO: e.g., Defect tracking, inspection results]

Baseline: [TODO: Current performance level]

Target Date: [TODO: Achievement date]

Responsible: [TODO: Role/Person]

Resources Required: [TODO: Resources needed]

Monitoring Frequency: [TODO: e.g., Monthly]

Status: [TODO: On track / At risk / Behind]

12.3.3 Objective 3: [TODO: Process Performance]

Description: [TODO: e.g., Improve on-time delivery to 95%]

Measurable Target: [TODO: Specific numeric target]

Measurement Method: [TODO: e.g., Delivery tracking system]

Baseline: [TODO: Current performance level]

Target Date: [TODO: Achievement date]

Responsible: [TODO: Role/Person]

Resources Required: [TODO: Resources needed]

Monitoring Frequency: [TODO: e.g., Monthly]

Status: [TODO: On track / At risk / Behind]

12.3.4 Objective 4: [TODO: Continual Improvement]

Description: [TODO: e.g., Implement 10 process improvement initiatives]

Measurable Target: [TODO: Specific numeric target]

Measurement Method: [TODO: e.g., Improvement project tracking]

Baseline: [TODO: Current performance level]

Target Date: [TODO: Achievement date]

Responsible: [TODO: Role/Person]

Resources Required: [TODO: Resources needed]

Monitoring Frequency: [TODO: e.g., Quarterly]

Status: [TODO: On track / At risk / Behind]

12.4 Function-Level Quality Objectives

12.4.1 Sales and Marketing

Objective: [TODO: e.g., Increase customer retention rate to 90%]

Target: [TODO: Specific target]

Measurement: [TODO: Method]

Responsible: Sales Manager

Review: [TODO: Frequency]

12.4.2 Operations/Production

Objective: [TODO: e.g., Achieve first-pass yield of 98%]

Target: [TODO: Specific target]

Measurement: [TODO: Method]

Responsible: Operations Manager

Review: [TODO: Frequency]

12.4.3 Quality Assurance

Objective: [TODO: e.g., Complete 100% of planned internal audits on schedule]

Target: [TODO: Specific target]

Measurement: [TODO: Method]

Responsible: Quality Manager

Review: [TODO: Frequency]

12.4.4 Purchasing

Objective: [TODO: e.g., Maintain supplier quality rating 95%]

Target: [TODO: Specific target]

Measurement: [TODO: Method]

Responsible: Purchasing Manager

Review: [TODO: Frequency]

12.4.5 [TODO: Other Functions]

Objective: [TODO: Define objective]

Target: [TODO: Specific target]

Measurement: [TODO: Method]

Responsible: [TODO: Role]

Review: [TODO: Frequency]

12.5 Planning to Achieve Quality Objectives

12.5.1 Action Planning

For each quality objective, planning includes:

What will be done: - [TODO: Specific actions and initiatives]

What resources will be required: - [TODO: Human, financial, infrastructure, technology resources]

Who will be responsible: - [TODO: Assign clear ownership]

When it will be completed: - [TODO: Milestones and target dates]

How the results will be evaluated: - [TODO: Measurement methods and success criteria]

12.5.2 Example Action Plan Template

Objective	Actions	Resources	Responsible	Timeline	Evaluation Method
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

12.6 Monitoring and Measurement

12.6.1 Performance Tracking

Data Collection: - [TODO: Define data collection methods and frequency]

Data Analysis: - [TODO: Define analysis methods and tools]

Reporting: - [TODO: Define reporting format and frequency]

12.6.2 Performance Dashboard

[TODO: Create or reference performance dashboard showing objective status]

Objective	Target	Current	Trend	Status	Last Update
[TODO]	[TODO]	[TODO]	↑/↓/→	[TODO]	[TODO]

12.7 Review and Update

12.7.1 Review Process

Quality objectives are reviewed: - **Monthly:** Progress review by responsible persons - **Quarterly:** Management review of all objectives - **Annually:** Comprehensive review and update - **As needed:** When circumstances change

12.7.2 Update Triggers

Objectives may be updated when: - Objectives are achieved ahead of schedule - Objectives become unachievable - Business strategy changes - Context or risks change significantly - New opportunities arise

12.7.3 Update Process

1. Propose objective changes with justification
2. Review by Quality Manager
3. Approval by Top Management
4. Communication to affected personnel
5. Update documentation and tracking systems

12.8 Communication

12.8.1 Internal Communication

Quality objectives communicated through: - **All-hands meetings:** [TODO: Frequency] - **Department meetings:** [TODO: Frequency] - **Intranet:** Objectives posted and updated - **Performance dashboards:** Visual displays - **Individual objectives:** Cascaded to personal goals

12.8.2 Ensuring Understanding

Personnel understand: - What the objectives are - Why they are important - How they contribute to achievement - Current status and progress

12.9 Integration with Other Processes

Quality objectives link to: - **Quality policy (5.2):** Objectives support policy - **Risk management (6.1):** Objectives address risks and opportunities - **Resource planning (7.1):** Resources allocated to achieve objectives - **Operational planning (8.1):** Operations designed to meet objectives - **Performance evaluation (9.1):** Objectives measured and monitored - **Management review (9.3):** Objective achievement reviewed - **Improvement (10.3):** Objectives drive improvement

12.10 Documentation

- **Document location:** [TODO: Specify location]
- **Related documents:** Quality policy, strategic plan, performance reports
- **Version control:** Maintained according to Clause 7.5
- **Retention:** [TODO: Define retention period]

Next Steps: 1. Establish quality objectives at organizational and functional levels 2. Ensure objectives are SMART and aligned with policy 3. Develop action plans for each objective 4. Assign responsibilities and allocate resources 5. Implement monitoring and reporting systems 6. Review progress regularly and adjust as needed

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Chapter 13

Planning of Changes

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13.1 Purpose

This document defines the process for planning changes to the quality management system in accordance with ISO 9001:2015 Clause 6.3.

13.2 Change Management Process

13.2.1 Types of Changes

QMS changes may include: - Process changes - Organizational structure changes - Technology or system changes - Product or service changes - Resource changes - Documentation changes - Scope changes

13.2.2 Change Initiation

Changes may be initiated by: - Management review decisions - Audit findings - Corrective actions - Improvement initiatives - Risk assessments - Customer requirements - Regulatory changes - Strategic decisions

13.3 Change Planning Requirements

13.3.1 Purpose of Change (6.3a)

Document: - Why the change is needed - What problem it solves or opportunity it addresses - Expected benefits - Alignment with quality objectives and strategy

13.3.2 Potential Consequences (6.3b)

Assess: - Impact on QMS effectiveness - Impact on product/service conformity - Impact on customer satisfaction - Impact on compliance - Risks introduced by the change - Resource implications

13.3.3 QMS Integrity (6.3c)

Ensure: - QMS remains effective during and after change - No gaps in QMS coverage - Continued conformity to ISO 9001 - Maintained process interactions - Continued achievement of intended results

13.3.4 Resource Availability (6.3d)

Identify: - Human resources needed - Financial resources required - Infrastructure and equipment needs - Time requirements - Training needs - External support requirements

13.3.5 Responsibilities and Authorities (6.3e)

Define: - Who is responsible for change implementation - Who has authority to approve change - Who needs to be consulted - Who needs to be informed - Changes to organizational roles if applicable

13.4 Change Request and Approval

13.4.1 Change Request Form

Required Information: - Change description - Justification and purpose - Affected processes/areas - Impact assessment - Resource requirements - Implementation plan - Risk assessment - Proposed timeline

13.4.2 Approval Process

Approval Authority: - Minor changes: [TODO: Define authority level] - Major changes: Top Management - Critical changes: [TODO: Define authority level]

Approval Criteria: - Change supports quality objectives - Resources are available - Risks are acceptable - QMS integrity maintained - Benefits outweigh costs

13.5 Change Implementation Planning

13.5.1 Implementation Plan

Plan includes: - Detailed implementation steps - Timeline and milestones - Resource allocation - Responsibilities assignment - Communication plan - Training requirements - Verification and validation activities - Rollback plan if needed

13.5.2 Risk Management

Address: - Risks introduced by change - Mitigation measures - Contingency plans - Monitoring during implementation

13.5.3 Communication

Communicate to: - Affected personnel - Customers (if applicable) - Suppliers (if applicable) - Other interested parties

Communication includes: - What is changing - Why it is changing - When it will change - How it affects them - What actions they need to take

13.6 Implementation and Verification

13.6.1 Implementation

- Execute according to plan
- Monitor progress
- Address issues promptly
- Document implementation

13.6.2 Verification

Verify: - Change implemented as planned - Intended results achieved - No unintended consequences - QMS integrity maintained - Resources adequate

13.6.3 Validation

Validate: - Change effectiveness - Objectives met - Customer requirements still met - Compliance maintained

13.7 Documentation Updates

13.7.1 Affected Documentation

Update: - Quality manual (if applicable) - Procedures and work instructions - Forms and templates - Process maps - Organizational charts - Training materials - External documents (if needed)

13.7.2 Document Control

- Follow documented information control (Clause 7.5)
- Version control
- Distribution of updated documents
- Obsolete document removal

13.8 Post-Implementation Review

13.8.1 Review Activities

Conduct: - Effectiveness evaluation - Lessons learned capture - Feedback collection - Performance monitoring - Adjustment if needed

13.8.2 Review Timing

- [TODO: Define review period, e.g., 30 days, 90 days after implementation]

13.8.3 Review Responsibilities

- Change owner conducts review
- Quality Manager verifies
- Results reported to management

13.9 Change Register

13.9.1 Change Tracking

Maintain register with: - Change ID - Change description - Initiator - Date requested - Approval status - Implementation status - Completion date - Effectiveness status

Change ID	Description	Initiator	Request Date	Status	Completion	Effective
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

Next Steps: 1. Establish change management process 2. Create change request form and approval workflow 3. Train personnel on change management 4. Implement change tracking system 5. Conduct post-implementation reviews 6. Continuously improve change process

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Chapter 14

Resources

Document-ID: 0300
Owner: {{ meta.owner }}
Version: {{ meta.version }}
Status: Draft
Classification: Internal
Last Update: {{ meta.date }}

14.1 Purpose

This document defines how {{ meta.organization }} determines and provides resources needed for the quality management system in accordance with ISO 9001:2015 Clause 7.1.

14.2 Resource Planning Process

14.2.1 Resource Identification

Resources needed for QMS: - People (Clause 7.2) - Infrastructure (Clause 7.1.3) - Environment for operation of processes (Clause 7.1.4) - Monitoring and measuring resources (Clause 7.1.5) - Organizational knowledge (Clause 7.1.6)

14.2.2 Resource Assessment

Consider: - Capabilities of existing internal resources - Constraints on existing internal resources - What needs to be obtained from external providers - Current vs. future resource needs

14.2.3 Resource Allocation

Process: 1. Identify resource requirements 2. Assess current resources 3. Identify gaps 4. Plan resource acquisition or development 5. Allocate resources to processes and objectives 6. Monitor resource adequacy 7. Adjust as needed

14.3 People (7.2)

14.3.1 Competence Requirements

Determine: - Competence needed for each role affecting QMS - Education, training, and experience requirements - Skills and knowledge requirements

See: Competence, Training, and Awareness (Document 0310)

14.3.2 Staffing Levels

Assess: - Number of personnel needed for each function - Workload and capacity - Peak demand periods - Backup and coverage needs

Current Staffing: - [TODO: Document current staffing levels by function]

Staffing Gaps: - [TODO: Identify any staffing shortfalls]

14.3.3 Recruitment and Selection

Process: - Define position requirements - Recruit qualified candidates - Assess competence during selection - Verify qualifications and experience - Onboard and train new personnel

14.4 Infrastructure (7.1.3)

14.4.1 Infrastructure Categories

Buildings and Workspace: - Office space - Production facilities - Warehouses - Laboratories - [TODO: List specific facilities]

Equipment: - Production equipment - Testing equipment - IT hardware - Vehicles - [TODO: List specific equipment]

Transportation: - Delivery vehicles - Company vehicles - Logistics arrangements

Information and Communication Technology: - Computer systems - Software applications - Network infrastructure - Communication systems - [TODO: List specific IT resources]

14.4.2 Infrastructure Management

Maintenance: - Preventive maintenance schedules - Corrective maintenance procedures - Equipment calibration (see 7.1.5) - Facility upkeep

Adequacy Assessment: - Regular assessment of infrastructure adequacy - Identification of infrastructure needs - Planning for infrastructure improvements - Budget allocation for infrastructure

Current Infrastructure: - [TODO: Document current infrastructure]

Infrastructure Gaps: - [TODO: Identify any infrastructure shortfalls]

14.5 Environment for Operation of Processes (7.1.4)

14.5.1 Environmental Factors

Physical Factors: - Temperature and humidity control - Lighting - Noise levels - Cleanliness - Air quality

Social Factors: - Non-discriminatory environment - Calm and non-confrontational atmosphere - Stress management - Work-life balance

Psychological Factors: - Stress reduction - Burnout prevention - Recognition and reward - Job satisfaction

Other Factors: - [TODO: Identify other relevant environmental factors]

14.5.2 Environment Management

Monitoring: - Regular assessment of work environment - Employee feedback on environment - Environmental measurements where applicable

Improvement: - Actions to improve work environment - Investment in environmental improvements - Addressing employee concerns

Current Environment: - [TODO: Describe current work environment]

Environment Improvements Needed: - [TODO: Identify any environmental improvements needed]

14.6 Monitoring and Measuring Resources (7.1.5)

14.6.1 Resource Requirements

Determine: - What needs to be monitored and measured - What resources are needed for monitoring and measurement - Accuracy and precision requirements

See: Monitoring and Measuring Resources (Document 0320)

14.6.2 Resource Types

- Measurement equipment and instruments
- Testing equipment
- Inspection tools
- Software for data analysis
- Calibration standards

14.6.3 Resource Management

- Calibration and verification
- Maintenance and care
- Suitability verification
- Records of fitness for purpose

14.7 Organizational Knowledge (7.1.6)

14.7.1 Knowledge Identification

Determine: - Knowledge needed to operate processes - Knowledge needed to achieve product/service conformity - Current organizational knowledge - Knowledge gaps

See: Organizational Knowledge (Document 0330)

14.7.2 Knowledge Sources

Internal: - Employee experience and expertise - Lessons learned - Process documentation - Intellectual property - Standards and best practices

External: - Industry standards - Academic research - Conferences and training - Benchmarking - Consultants and experts

14.7.3 Knowledge Management

- Capture and document knowledge
- Share knowledge across organization
- Protect knowledge from loss
- Update knowledge as needed
- Acquire new knowledge

14.8 External Providers

14.8.1 External Resource Needs

Identify: - Resources that must be obtained externally - Temporary vs. permanent external resources - Specialized expertise or equipment

14.8.2 External Provider Management

Process: - Identify qualified external providers - Evaluate and select providers - Define requirements in contracts - Monitor provider performance - Manage provider relationships

See: Control of Externally Provided Processes, Products, and Services (Clause 8.4)

14.9 Resource Budgeting

14.9.1 Budget Planning

Annual budget includes: - Personnel costs (salaries, benefits, training) - Infrastructure costs (facilities, equipment, maintenance) - Technology costs (IT systems, software licenses) - External provider costs - Monitoring and measurement resources - Improvement initiatives

14.9.2 Budget Allocation

Priorities: 1. Critical QMS requirements 2. Compliance and regulatory needs 3. Customer requirements 4. Improvement initiatives 5. [TODO: Define organization-specific priorities]

14.9.3 Budget Monitoring

- Track actual vs. budgeted resource expenditure
- Identify variances
- Adjust allocations as needed
- Report to management

14.10 Resource Adequacy Review

14.10.1 Review Process

Frequency: [TODO: e.g., Quarterly, annually]

Assess: - Are current resources adequate for QMS needs? - Are resources being used effectively? - What additional resources are needed? - What resource constraints exist? - How can resource efficiency be improved?

14.10.2 Review Responsibilities

- Process owners assess process resource needs
- Quality Manager consolidates resource assessment
- Top Management reviews and approves resource plans
- Management review includes resource adequacy (Clause 9.3)

14.10.3 Resource Adjustments

Actions: - Acquire additional resources - Reallocate existing resources - Improve resource utilization - Eliminate unnecessary resource use - Develop internal capabilities

14.11 Documentation

- **Resource inventory:** Current resources documented
- **Resource plans:** Future resource needs and acquisition plans
- **Budget documents:** Resource budget and expenditure tracking
- **Adequacy assessments:** Resource adequacy review records

Next Steps: 1. Conduct comprehensive resource assessment 2. Identify resource gaps and needs 3. Develop resource acquisition plans 4. Allocate budget for resources 5. Implement resource monitoring process 6. Review resource adequacy regularly

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Chapter 15

Competence, Training, and Awareness

Document-ID: 0310
Owner: {{ meta.owner }}
Version: {{ meta.version }}
Status: Draft
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15.1 Purpose

This document defines how {{ meta.organization }} ensures competence of personnel and promotes awareness of the quality management system in accordance with ISO 9001:2015 Clauses 7.2 and 7.3.

15.2 Competence Management (7.2)

15.2.1 Competence Requirements

Determine competence needed for: - Persons doing work under the organization's control - Work affecting QMS performance and effectiveness - Work affecting ability to meet product/service requirements

15.2.2 Competence Criteria

Competence based on: - **Education:** Formal education and qualifications - **Training:** Job-specific training and certifications - **Experience:** Relevant work experience - **Skills:** Demonstrated abilities and proficiencies

15.2.3 Competence Matrix

Role/Position	Education	Training	Experience	Skills	Competence Verification
[TODO: Role]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

Role/Position	Education	Training	Experience	Skills	Competence Verification
Quality Manager	[TODO]	ISO 9001 Lead Auditor	[TODO]	[TODO]	[TODO]
Process Owner [TODO: Add all relevant roles]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

15.3 Ensuring Competence

15.3.1 Competence Assessment

Methods: - Review of qualifications and credentials - Skills testing and evaluation - Performance observation - Competence interviews - Certification verification - [TODO: Define organization-specific methods]

Frequency: - Initial assessment during hiring - Periodic reassessment: [TODO: Define frequency] - After significant changes in role or processes - Following training completion

15.3.2 Actions to Acquire Competence

When competence gaps identified:

Training: - Internal training programs - External training courses - On-the-job training - E-learning and online courses - Workshops and seminars

Mentoring and Coaching: - Pairing with experienced personnel - Job shadowing - Coaching programs

Hiring: - Recruit personnel with required competence - Verify qualifications during selection

Contracting: - Engage external experts or consultants - Temporary specialized personnel

Other Actions: - Job rotation for skill development - Special assignments - Self-study programs - [TODO: Define other actions]

15.3.3 Effectiveness Evaluation

Evaluate effectiveness of actions taken:

Methods: - Post-training assessment (tests, quizzes) - Performance observation - Work quality review - Supervisor evaluation - Self-assessment - Customer feedback - Error rates and quality metrics

Timing: - Immediately after training - [TODO: Define follow-up period, e.g., 30 days, 90 days] - Ongoing performance monitoring

Criteria for Effectiveness: - Personnel can perform required tasks - Work meets quality standards - Reduced errors or nonconformities - Improved performance metrics - Positive feedback from supervisors/customers

15.4 Training Program

15.4.1 Training Needs Assessment

Identify training needs from: - Competence gap analysis - New employee onboarding - New processes or technologies - Audit findings - Nonconformities and errors - Performance reviews - Regulatory changes - Strategic initiatives

Assessment Process: 1. Identify competence requirements 2. Assess current competence levels 3. Identify gaps 4. Prioritize training needs 5. Develop training plan

15.4.2 Training Plan

Annual training plan includes: - Training objectives - Target audience - Training content and curriculum - Training methods (classroom, online, OJT) - Training schedule - Trainers/instructors - Resources required - Evaluation methods

15.4.3 Training Delivery

Training Methods: - **Classroom training:** Instructor-led sessions - **On-the-job training:** Hands-on learning - **E-learning:** Online courses and modules - **Workshops:** Interactive skill-building sessions - **Webinars:** Virtual training sessions - **Self-study:** Reading materials, videos - **External courses:** Industry training programs

Training Topics: - QMS overview and ISO 9001 requirements - Quality policy and objectives - Process-specific procedures - Product/service requirements - Equipment operation - Safety and compliance - Problem-solving and improvement methods - [TODO: Add organization-specific topics]

15.4.4 Training Records

Maintain records of: - Training attended (course name, date, duration) - Trainer/provider - Training materials used - Assessment results - Competence verification - Effectiveness evaluation

Record Format: [TODO: Define format, e.g., training matrix, individual training files]

Record Location: [TODO: Define location]

Retention: [TODO: Define retention period]

15.5 Awareness (7.3)

15.5.1 Awareness Requirements

Ensure personnel are aware of:

Quality Policy (7.3a): - Content and meaning of quality policy - How policy applies to their work - Their role in supporting policy

Relevant Quality Objectives (7.3b): - Quality objectives relevant to their function - Current status of objectives - How they contribute to achievement

Contribution to QMS Effectiveness (7.3c): - How their work affects QMS performance - Importance of conforming to QMS requirements - Their role in achieving intended results

Implications of Not Conforming (7.3d): - Consequences of not following QMS requirements - Impact on product/service quality - Impact on customers and organization - Personal accountability

15.5.2 Awareness Program

Communication Methods: - **Onboarding:** QMS awareness in new employee orientation - **Training:** QMS awareness included in all training - **Meetings:** Regular communication in team meetings - **Visual displays:** Posters, notice boards, digital displays - **Intranet:** QMS information on company intranet - **Newsletters:** Regular QMS updates and reminders - **Toolbox talks:** Brief awareness sessions - **Performance reviews:** QMS awareness discussed

Communication Frequency: - Ongoing and continuous - Formal awareness sessions: [TODO: Define frequency] - Reminders and reinforcement: [TODO: Define frequency]

15.5.3 Awareness Assessment

Verify awareness through: - Surveys and questionnaires - Interviews and discussions - Observation of behavior - Audit findings - Performance indicators - [TODO: Define assessment methods]

Assessment Frequency: [TODO: e.g., Annually, during audits]

15.5.4 Awareness Improvement

Actions to improve awareness: - Enhanced communication - Additional training - Visual management - Recognition of good practices - Addressing awareness gaps identified

15.6 Competence and Training Records

15.6.1 Individual Training Files

Maintain for each person: - Personal information - Education and qualifications - Training history - Competence assessments - Certifications and licenses - Performance evaluations

15.6.2 Training Matrix

Track training status:

Name	Role	Required Training	Completed	Due Date	Status
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]	Current/Overdue

15.6.3 Competence Records

Document: - Competence requirements met - Evidence of competence (certificates, assessments) - Date of competence verification - Next review date

15.7 Responsibilities

15.7.1 Human Resources

- Maintain training records

- Coordinate training programs
- Track training completion
- Support competence assessment

15.7.2 Managers/Supervisors

- Identify training needs for their teams
- Ensure personnel attend required training
- Evaluate training effectiveness
- Verify competence of their personnel

15.7.3 Quality Manager

- Define QMS training requirements
- Develop QMS training materials
- Deliver QMS training
- Monitor overall training effectiveness

15.7.4 Employees

- Participate in required training
- Apply learning to their work
- Maintain their competence
- Seek additional training when needed

15.8 Review and Improvement

15.8.1 Training Program Review

Review annually: - Training needs assessment process - Training effectiveness - Training completion rates - Competence levels achieved - Awareness levels - Training program improvements needed

15.8.2 Continuous Improvement

Improve through: - Feedback from trainees - Training effectiveness data - Benchmarking with best practices - New training methods and technologies - Updated training content

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Next Steps: 1. Define competence requirements for all roles 2. Assess current competence levels 3. Develop annual training plan 4. Implement training programs 5. Evaluate training effectiveness 6. Maintain competence and training records 7. Promote ongoing QMS awareness

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Chapter 16

Communication

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Version: {{ meta.version }}
Status: Draft
Classification: Internal
Last Update: {{ meta.date }}

16.1 Purpose

This document defines internal and external communications relevant to the quality management system in accordance with ISO 9001:2015 Clause 7.4.

16.2 Communication Planning

16.2.1 Communication Determination

For each communication, determine: - **What:** Content and subject matter - **When:** Timing and frequency - **With whom:** Target audience (internal/external) - **How:** Communication method and channel - **Who:** Responsible person or role

16.3 Internal Communication

16.3.1 QMS Performance Communication

What: QMS performance, effectiveness, and improvement **When:** [TODO: e.g., Monthly, quarterly] **With whom:** All personnel, management **How:** [TODO: e.g., Meetings, intranet, dashboards] **Who:** Quality Manager

16.3.2 Quality Policy and Objectives

What: Quality policy, quality objectives, and progress **When:** [TODO: e.g., Quarterly, annually, ongoing] **With whom:** All personnel **How:** [TODO: e.g., All-hands meetings, intranet, posters]

Who: Top Management, Quality Manager

16.3.3 Process Performance

What: Process performance indicators and results **When:** [TODO: e.g., Monthly] **With whom:** Process owners, relevant personnel **How:** [TODO: e.g., Process review meetings, reports] **Who:** Process Owners

16.3.4 Audit Results

What: Internal audit findings and corrective actions **When:** After each audit **With whom:** Auditees, management **How:** Audit reports, meetings **Who:** Quality Manager, Auditors

16.3.5 Nonconformities and Corrective Actions

What: Nonconformities, root causes, corrective actions **When:** As they occur **With whom:** Affected personnel, management **How:** [TODO: e.g., Nonconformity reports, meetings] **Who:** Quality Manager, Process Owners

16.3.6 Changes to QMS

What: Planned changes to QMS, processes, or requirements **When:** Before and during implementation **With whom:** Affected personnel **How:** [TODO: e.g., Meetings, emails, training] **Who:** Change Owner, Quality Manager

16.3.7 Management Review Results

What: Management review decisions and actions **When:** After each management review **With whom:** All personnel, relevant stakeholders **How:** [TODO: e.g., Summary communication, meetings] **Who:** Top Management, Quality Manager

16.3.8 Training and Awareness

What: Training opportunities, QMS awareness messages **When:** [TODO: e.g., Ongoing, as scheduled] **With whom:** All personnel **How:** [TODO: e.g., Training calendar, emails, intranet] **Who:** HR, Quality Manager

16.3.9 [TODO: Other Internal Communications]

What: [TODO: Define content] **When:** [TODO: Define timing] **With whom:** [TODO: Define audience] **How:** [TODO: Define method] **Who:** [TODO: Define responsibility]

16.4 External Communication

16.4.1 Customer Communication (8.2.1)

What: Product/service information, inquiries, orders, feedback, complaints **When:** As needed, ongoing **With whom:** Customers **How:** [TODO: e.g., Email, phone, portal, meetings] **Who:** Sales, Customer Service

See: Customer Communication (Clause 8.2.1) for detailed requirements

16.4.2 Supplier Communication

What: Requirements, performance, quality issues, changes **When:** [TODO: e.g., As needed, quarterly reviews] **With whom:** Suppliers and external providers **How:** [TODO: e.g., Email, meetings, supplier portal] **Who:** Purchasing Manager

16.4.3 Regulatory and Certification Bodies

What: Compliance information, audit arrangements, changes **When:** As required, during audits **With whom:** Regulatory authorities, certification bodies **How:** [TODO: e.g., Formal submissions, audit meetings] **Who:** Quality Manager, Top Management

16.4.4 Interested Parties

What: QMS performance, certifications, capabilities **When:** [TODO: e.g., As needed, annually] **With whom:** Stakeholders identified in Clause 4.2 **How:** [TODO: e.g., Reports, meetings, website] **Who:** [TODO: Define responsibility]

16.4.5 Public and Media

What: Company information, quality achievements, certifications **When:** As appropriate **With whom:** General public, media **How:** [TODO: e.g., Website, press releases, social media] **Who:** [TODO: e.g., Marketing, Communications]

16.4.6 [TODO: Other External Communications]

What: [TODO: Define content] **When:** [TODO: Define timing] **With whom:** [TODO: Define audience] **How:** [TODO: Define method] **Who:** [TODO: Define responsibility]

16.5 Communication Methods and Channels

16.5.1 Internal Communication Methods

Meetings: - Management review meetings - Department meetings - Team meetings - Toolbox talks - Town halls

Digital Channels: - Company intranet - Email - Collaboration platforms - Digital dashboards - Internal social media

Physical Channels: - Notice boards - Posters and displays - Newsletters - Memos and circulars

Direct Communication: - One-on-one discussions - Performance reviews - Training sessions

16.5.2 External Communication Methods

Digital: - Email - Website - Customer portal - Supplier portal - Electronic data interchange (EDI)

Meetings: - Customer meetings - Supplier meetings - Audit meetings - Conferences

Documentation: - Letters and formal correspondence - Reports - Certificates - Contracts

Phone: - Customer service calls - Technical support - Sales inquiries

16.6 Communication Effectiveness

16.6.1 Ensuring Effective Communication

Communication is effective when: - Message is clear and understood - Reaches intended audience - Delivered in timely manner - Appropriate method used - Feedback mechanism exists

16.6.2 Communication Verification

Verify effectiveness through: - Acknowledgment of receipt - Feedback and questions - Surveys and assessments - Observation of behavior changes - Achievement of communication objectives

16.6.3 Communication Improvement

Improve communication through: - Feedback from recipients - Communication audits - Benchmarking - New communication technologies - Training on communication skills

16.7 Communication Records

16.7.1 Records to Maintain

Internal: - Meeting minutes - Email communications (as appropriate) - Training records - Announcements and notices

External: - Customer correspondence - Supplier communications - Regulatory submissions - Audit correspondence - Contracts and agreements

16.7.2 Record Management

- **Storage:** [TODO: Define storage location and method]
- **Retention:** [TODO: Define retention periods]
- **Access:** [TODO: Define access controls]
- **Protection:** Ensure confidentiality where required

16.8 Responsibilities

16.8.1 Top Management

- Communicate quality policy and strategic direction
- Communicate importance of QMS
- Participate in management review communication

16.8.2 Quality Manager

- Coordinate QMS-related communications
- Communicate QMS performance
- Communicate audit results
- Facilitate management review communication

16.8.3 Process Owners

- Communicate process performance
- Communicate process changes
- Communicate with process stakeholders

16.8.4 All Personnel

- Participate in communication
- Provide feedback
- Communicate quality issues
- Follow communication protocols

16.8.5 [TODO: Other Roles]

- [TODO: Define communication responsibilities]

16.9 Communication Schedule

16.9.1 Regular Communications

Communication	Frequency	Responsible	Audience	Method
QMS Performance	[TODO]	Quality Manager	All personnel	[TODO]
Quality Objectives	[TODO]	Top Management	All personnel	[TODO]
Process Performance	[TODO]	Process Owners	Relevant personnel	[TODO]
Management Review	[TODO]	Top Management	All personnel	[TODO]
[TODO: Add more]				

16.9.2 Ad-Hoc Communications

- Nonconformities and urgent quality issues
- Customer complaints
- Regulatory changes
- Emergency situations
- [TODO: Define other ad-hoc communications]

16.10 Review and Improvement

16.10.1 Communication Review

Review communication effectiveness: - During management review - Through internal audits - Based on feedback - [TODO: Define review frequency]

16.10.2 Improvement Actions

- Update communication methods
- Enhance communication channels

- Improve communication content
- Increase communication frequency
- Provide communication training

Next Steps: 1. Complete communication planning for all relevant communications 2. Establish communication methods and channels 3. Assign communication responsibilities 4. Implement communication schedule 5. Monitor communication effectiveness 6. Continuously improve communication processes

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Chapter 17

Control of Documented Information

Document-ID: 0330
Owner: {{ meta.owner }}
Version: {{ meta.version }}
Status: Draft
Classification: Internal
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17.1 Purpose

This document defines how {{ meta.organization }} controls documented information in accordance with ISO 9001:2015 Clause 7.5.

17.2 Documented Information in QMS

17.2.1 Types of Documented Information

Required by ISO 9001: - Quality policy (5.2) - Quality objectives (6.2) - Scope of QMS (4.3) - Processes and their interactions (4.4) - Competence records (7.2) - Monitoring and measurement records (9.1) - Internal audit records (9.2) - Management review records (9.3) - Nonconformity and corrective action records (10.2) - [TODO: List all ISO 9001 required documented information]

Required by Organization: - Procedures and work instructions - Forms and templates - Process maps and flowcharts - Organizational charts - Specifications and standards - [TODO: List organization-specific documented information]

17.2.2 Document Hierarchy

Level 1: Quality Manual (if applicable) **Level 2:** Procedures **Level 3:** Work Instructions **Level 4:** Forms and Records

17.3 Document Identification (7.5.3.1)

17.3.1 Identification Requirements

Each document includes: - **Document title:** Clear, descriptive title - **Document ID:** Unique identifier - **Version number:** Current version - **Date:** Issue date or revision date - **Author/Owner:** Person responsible - **Approval:** Approver name and signature/date - **Status:** Draft, In Review, Approved, Obsolete - **Classification:** Internal, Confidential, Public

17.3.2 Document Numbering System

Format: [TODO: Define numbering format, e.g., XXX-YYY-ZZZ]

Example: - QMS-PRO-001: QMS Procedure 001 - QMS-WI-001: Work Instruction 001 - QMS-FORM-001: Form 001

17.4 Document Creation and Approval (7.5.3.1)

17.4.1 Document Creation Process

1. **Initiation:** Need for document identified
2. **Drafting:** Document author creates draft
3. **Review:** Relevant personnel review draft
4. **Revision:** Author incorporates feedback
5. **Approval:** Authorized person approves
6. **Release:** Document released for use
7. **Distribution:** Document distributed to users

17.4.2 Approval Authority

Document Type	Approval Authority
Quality Policy	Top Management
Procedures	Quality Manager
Work Instructions	Process Owner / Department Manager
Forms	Process Owner
[TODO: Add more]	[TODO: Define authority]

17.4.3 Review and Update (7.5.3.1)

Review Frequency: - **Regular:** [TODO: e.g., Annually, every 2 years] - **Triggered:** When changes occur in processes, requirements, or regulations - **After audits:** Based on audit findings - **As needed:** When issues identified

Review Process: 1. Document owner initiates review 2. Review for continued suitability and adequacy 3. Update if needed 4. Re-approve updated document 5. Communicate changes 6. Replace obsolete versions

17.5 Document Distribution and Access (7.5.3.2)

17.5.1 Availability

Documents available: - At point of use - To personnel who need them - In appropriate format (paper, electronic) - In timely manner

17.5.2 Distribution Methods

Electronic: - Company intranet/document management system - Shared network drives - Email distribution - Cloud-based platforms

Physical: - Controlled copies in work areas - Printed copies (controlled) - Binders and folders

17.5.3 Access Control

Define access levels: - **Public:** Available to all - **Internal:** Available to all employees - **Restricted:** Available to specific roles/departments - **Confidential:** Limited access, need-to-know basis

Access managed through: - [TODO: e.g., Document management system permissions, physical access controls]

17.6 Version Control (7.5.3.2)

17.6.1 Version Numbering

Format: [TODO: Define format, e.g., V1.0, V1.1, V2.0]

Version Changes: - **Major revision (e.g., V1.0 → V2.0):** Significant changes - **Minor revision (e.g., V1.0 → V1.1):** Minor changes, corrections

17.6.2 Change Documentation

Document changes through: - Revision history table in document - Change log or register - Change notices

Revision History Format:

Version	Date	Author	Description of Changes	Approved By
1.0	[TODO]	[TODO]	Initial release	[TODO]
1.1	[TODO]	[TODO]	[TODO: Changes]	[TODO]

17.6.3 Superseded Documents

When new version released: - Remove obsolete versions from use - Mark obsolete versions as "OBSOLETE" or "SUPERSEDED" - Retain obsolete versions for records (if required) - Communicate document changes

17.7 Protection of Documented Information (7.5.3.2)

17.7.1 Protection from Loss

Measures: - Regular backups of electronic documents - Redundant storage locations - Disaster recovery procedures - Physical security for paper documents

17.7.2 Protection from Unauthorized Changes

Measures: - Access controls and permissions - Check-in/check-out procedures - Audit trails of changes - Approval requirements for changes

17.7.3 Protection from Damage

Measures: - Secure storage (fire-proof, water-proof) - Environmental controls (temperature, humidity) - Handling procedures - Protective covers or binders

17.7.4 Confidentiality

For confidential documents: - Restricted access - Secure storage - Confidentiality agreements - Secure disposal

17.8 External Documents (7.5.3.2)

17.8.1 External Document Types

- Customer specifications and drawings
- Supplier documents
- Standards and regulations
- Codes and guidelines
- Technical references

17.8.2 External Document Control

Identify: - List of external documents used - Source and version - Location

Control: - Ensure current versions are used - Monitor for updates - Replace obsolete versions - Restrict distribution if required

External Document Register:

Document Title	Source	Version/Date	Location	Review Date
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

17.9 Records Control

17.9.1 Record Requirements

Records provide evidence of: - Conformity to requirements - Effective operation of QMS - Activities performed - Results achieved

17.9.2 Record Identification

Records include: - Unique identifier - Date created - Person responsible - Related process or activity

17.9.3 Record Storage

Storage requirements: - Secure location - Protected from damage and loss - Organized for easy retrieval - Appropriate format (paper, electronic)

Storage locations: [TODO: Define storage locations for different record types]

17.9.4 Record Retention

Retention periods:

Record Type	Retention Period	Disposal Method
Quality records	[TODO: e.g., 10 years]	[TODO]
Training records	[TODO]	[TODO]
Audit records	[TODO]	[TODO]
Calibration records	[TODO]	[TODO]
Customer records	[TODO]	[TODO]
[TODO: Add more]	[TODO]	[TODO]

17.9.5 Record Retrieval

Ensure records are: - Easily retrievable - Searchable (for electronic records) - Indexed or cataloged - Available to authorized personnel

17.9.6 Record Disposal

Disposal process: 1. Verify retention period expired 2. Obtain approval for disposal 3. Dispose securely (shred, delete) 4. Document disposal (if required)

17.10 Document Management System

17.10.1 System Description

Document management through: - [TODO: e.g., Electronic document management system, SharePoint, network drives, paper-based system]

System capabilities: - Version control - Access control - Search and retrieval - Audit trail - Backup and recovery

17.10.2 System Administration

Responsibilities: - **Document Control Coordinator:** [TODO: Name/Role] - **System Administrator:** [TODO: Name/Role] - **Document Owners:** Responsible for their documents

17.11 Master List of Documented Information

17.11.1 Document Register

Maintain register of all controlled documents:

Doc ID	Title	Type	Version	Date	Owner	Status	Location
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

17.11.2 Record Register

Maintain register of record types:

Record Type	Responsible	Storage Location	Retention	Disposal
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

17.12 Responsibilities

17.12.1 Quality Manager

- Overall responsibility for document control
- Approve document control procedures
- Monitor document control effectiveness

17.12.2 Document Control Coordinator

- Maintain document register
- Manage document distribution
- Control document versions
- Archive obsolete documents

17.12.3 Document Owners

- Create and update their documents
- Ensure document accuracy
- Initiate document reviews
- Approve changes (within authority)

17.12.4 All Personnel

- Use current versions of documents
- Report document issues
- Follow document control procedures
- Protect documents from damage

17.13 Training

Personnel trained on: - Document control procedures - How to access documents - Version control requirements - Record keeping requirements - Document management system use

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Next Steps: 1. Establish document control procedures 2. Implement document management system 3. Create master list of documented information 4. Train personnel on document control 5. Conduct regular document reviews 6. Monitor document control effectiveness

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Chapter 18

Operational Planning and Control

Document-ID: 0400
Owner: {{ meta.owner }}
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Status: Draft
Classification: Internal
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18.1 Purpose

This document defines how {{ meta.organization }} conducts operational planning and control to meet requirements for the provision of products and services and to implement actions determined in Clause 6.

18.2 Operational Planning (8.1)

18.2.1 Planning Requirements

{{ meta.organization }} plans, implements, and controls the processes needed to: - Meet requirements for the provision of products and services - Implement actions determined in Clause 6 - Achieve intended outcomes

18.2.2 Planning Criteria

When planning, {{ meta.organization }} considers: - Requirements for products and services - Criteria for processes and product acceptance - Required resources - Control of processes according to criteria - Documented information as evidence

18.3 Process Control

18.3.1 Control Measures

{{ meta.organization }} controls planned changes and reviews consequences of unintended changes by: - Establishing process criteria - Implementing process control - Retaining documented information - Taking actions to mitigate adverse effects

18.3.2 Outsourced Processes

For outsourced processes, {{ meta.organization }} ensures: - Control or influence over outsourced processes - Type and extent of control are defined in QMS - Organization's responsibility remains

Outsourced Processes:

Process	External Provider	Control Measures	Responsible
[TODO]	[TODO]	[TODO]	[TODO]

18.4 Operational Performance

18.4.1 Performance Indicators

Key Performance Indicators (KPIs):

KPI	Target Value	Measurement Frequency	Responsible
On-time delivery	[TODO: e.g., 95%]	[TODO]	[TODO]
Lead time	[TODO]	[TODO]	[TODO]
Scrap rate	[TODO]	[TODO]	[TODO]
Customer satisfaction	[TODO]	[TODO]	[TODO]

18.4.2 Monitoring and Measurement

{{ meta.organization }} monitors and measures: - Process performance - Product conformity - Service quality - Customer satisfaction

18.5 Contingency Planning

18.5.1 Contingency Measures

For unforeseen situations: - Activation of contingency plans - Communication with affected parties - Implementation of interim measures - Restoration of normal operations

Contingency Scenarios: - [TODO: Define relevant contingency scenarios] - [TODO: e.g., Supplier failure, production outage, staff shortage]

18.6 Responsibilities

18.6.1 Operations Manager

- Overall responsibility for operational planning
- Approval of operational plans
- Monitoring operational performance

18.6.2 Process Owners

- Planning their processes
- Implementation of control measures
- Monitoring process performance
- Reporting deviations

Next Steps: 1. Define all operational processes 2. Establish process criteria 3. Implement control measures 4. Establish performance indicators 5. Monitor and measure regularly

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Chapter 19

Requirements for Products and Services

Document-ID: 0410
Owner: {{ meta.owner }}
Version: {{ meta.version }}
Status: Draft
Classification: Internal
Last Update: {{ meta.date }}

19.1 Purpose

This document defines how {{ meta.organization }} determines, reviews, and communicates requirements for products and services.

19.2 Customer Communication (8.2.1)

19.2.1 Communication Channels

{{ meta.organization }} communicates with customers regarding: - Information relating to products and services - Inquiries, contracts or order handling, including changes - Customer feedback, including customer complaints - Handling or controlling customer property - Specific requirements for contingency actions

Communication Methods: - [TODO: e.g., Email, phone, customer portal, personal meetings]

19.2.2 Customer Portal/System

If applicable: - **System:** [TODO: Name of customer communication system] - **Access:** [TODO: How customers obtain access] - **Features:** [TODO: Available features]

19.3 Determining Requirements (8.2.2)

19.3.1 Requirement Types

{{ meta.organization }} determines:

Customer Requirements: - Specified requirements (including delivery and post-delivery activities) - Unspecified but necessary requirements - Statutory and regulatory requirements - Contract or order-specific requirements

Organization Requirements: - Internal quality standards - Technical specifications - Performance requirements - Safety requirements

19.3.2 Requirement Capture

Process for capturing requirements: 1. Receive customer inquiry or requirement 2. Document requirements 3. Clarify requirements (if unclear) 4. Analyze requirements 5. Assess feasibility

Requirement Documentation: - [TODO: e.g., Requirement form, specification, customer specification]

19.4 Review of Requirements (8.2.3)

19.4.1 Review Process

Before committing to supply, {{ meta.organization }} reviews: - Requirements are defined - Contract or order requirements differing from previously expressed are resolved - Organization has ability to meet requirements

19.4.2 Review Criteria

Review includes: - **Technical Feasibility:** Can we manufacture/deliver it? - **Resource Availability:** Do we have required resources? - **Schedule:** Can we meet delivery date? - **Cost:** Is it economically feasible? - **Risks:** What risks exist?

19.4.3 Review Documentation

Documented information on: - Results of review - New requirements for products and services - Approval to accept order

Review Form:

Criterion	Assessment	Comments	Approved
Technical Feasibility	[TODO]	[TODO]	[TODO]
Resources	[TODO]	[TODO]	[TODO]
Schedule	[TODO]	[TODO]	[TODO]
Cost	[TODO]	[TODO]	[TODO]

19.4.4 Changes to Requirements

When requirements change: 1. Document change 2. Assess impact 3. Inform relevant persons 4. Update documented information 5. Approve change

19.5 Quotation Preparation

19.5.1 Quotation Process

Steps for quotation preparation: 1. Receive customer inquiry 2. Analyze requirements 3. Check feasibility 4. Calculate costs 5. Create quotation 6. Review and approve quotation 7. Send quotation to customer

19.5.2 Quotation Content

Quotation contains: - Product description/service description - Technical specifications - Scope of delivery - Delivery date - Price and payment terms - Validity period - General terms and conditions

19.6 Contract Management

19.6.1 Contract Conclusion

Before contract conclusion: - Final review of all requirements - Clarification of open points - Approval by authorized person - Contract signing

19.6.2 Contract Monitoring

During contract period: - Monitoring contract fulfillment - Management of changes - Communication with customers - Documentation of deviations

19.7 Responsibilities

19.7.1 Sales/Customer Service

- Customer communication
- Requirement capture
- Quotation preparation
- Contract management

19.7.2 Technical Department

- Technical feasibility review
- Specification creation
- Technical support

19.7.3 Quality Management

- Review of quality requirements
- Ensuring conformity
- Documentation

Next Steps: 1. Establish customer communication process 2. Define requirement capture methods 3. Implement review process 4. Train staff in requirement management 5. Monitor process effectiveness

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Chapter 20

Design and Development of Products and Services

Document-ID: 0420
Owner: {{ meta.owner }}
Version: {{ meta.version }}
Status: Draft
Classification: Internal
Last Update: {{ meta.date }}

20.1 Purpose

This document defines how {{ meta.organization }} designs and develops products and services to ensure they meet requirements.

20.2 Design Planning (8.3.2)

20.2.1 Development Process

{{ meta.organization }} plans and controls design and development by: - Determining design and development stages - Determining required reviews and validations - Defining responsibilities and authorities - Considering resource needs - Controlling interfaces between involved persons - Involving customers and users - Requirements for subsequent provision - Expected level of control - Documented information as evidence

20.2.2 Development Phases

Typical Development Phases:

Phase	Activities	Outputs	Responsible
1. Concept	Ideation, feasibility study	Concept document	[TODO]

Phase	Activities	Outputs	Responsible
2. Planning	Requirements analysis, project plan	Specification, project plan	[TODO]
3. Design	Detailed design, specifications	Design drawings	[TODO]
4. Development	Prototype building, tests	Prototype, test reports	[TODO]
5. Validation	Validation tests, release	Validation report	[TODO]
6. Launch	Production ramp-up, market launch	Series product	[TODO]

20.3 Design Inputs (8.3.3)

20.3.1 Input Requirements

{{ meta.organization }} determines requirements essential for specific types of products and services: - Functional and performance requirements - Information from previous similar developments - Statutory and regulatory requirements - Standards or codes of practice - Potential consequences of failure - Customer-specific requirements

20.3.2 Input Documentation

Design inputs documented in: - Requirements specification - Customer specifications - Technical requirements - Regulatory requirements

Inputs must be: - Complete - Unambiguous - Not contradictory - Verifiable

20.4 Design Controls (8.3.4)

20.4.1 Control Measures

{{ meta.organization }} applies controls to ensure: - Results to be achieved are defined - Reviews are conducted - Validations are conducted - Responsibilities and authorities are defined - Internal and external resource needs are considered - Interfaces are controlled - Customers and users are involved - Requirements are met - Problems are resolved - Documented information is retained

20.4.2 Design Reviews

Regular design reviews at each phase: - **Participants:** [TODO: e.g., Development, Quality, Production, Sales] - **Frequency:** [TODO: e.g., At end of each phase] - **Criteria:** Achievement of phase objectives

Review Checklist: - Are all requirements considered? - Are risks identified and assessed? - Are solutions technically feasible? - Are resources available? - Is schedule realistic?

20.5 Design Outputs (8.3.5)

20.5.1 Output Requirements

{{ meta.organization }} ensures design outputs: - Meet input requirements - Are adequate for subsequent processes - Include monitoring and measurement requirements - Specify acceptance criteria - Specify characteristics for safe and proper provision

20.5.2 Output Documentation

Design outputs documented in: - Technical drawings - Specifications - Bills of materials (BOM) - Work instructions - Inspection instructions - Packaging instructions

20.6 Design Changes (8.3.6)

20.6.1 Change Management

{{ meta.organization }} identifies, reviews, and controls changes during or after design and development: - Changes are documented - Impacts are assessed - Changes are reviewed and approved - Actions to prevent adverse impacts are taken - Documented information is retained

20.6.2 Change Process

Steps in change process: 1. Submit change request 2. Assess change (technical, cost, schedule) 3. Conduct impact analysis 4. Approve/reject change 5. Implement change 6. Verify change 7. Update documentation 8. Inform affected parties

Change Request Form:

Field	Description
Change ID	Unique identifier
Requestor	Name and date
Description	What should be changed?
Justification	Why is change necessary?
Impacts	Technical, cost, schedule
Approval	Name, signature, date

20.7 Verification and Validation

20.7.1 Verification (8.3.4)

Verification ensures design outputs meet input requirements: - **Methods:** Calculations, comparisons, tests, alternative designs - **Timing:** At end of each development phase - **Documentation:** Verification reports

20.7.2 Validation (8.3.4)

Validation ensures products/services meet intended application: - **Methods:** Field tests, pilot production, customer tests - **Timing:** Before delivery or implementation - **Documentation:** Validation reports

Validation Criteria: - Functionality under real conditions - Usability - Reliability - Safety - Performance

20.8 Development Documentation

20.8.1 Required Documentation

For each development project: - Development plan - Requirements specification - Design documents - Verification and validation reports - Change logs - Release documentation

20.8.2 Document Retention

Development documentation retained for: - [TODO: e.g., Product lifetime + X years]

20.9 Responsibilities

20.9.1 Development Manager

- Overall responsibility for development projects
- Approval of development plans
- Resource allocation
- Progress monitoring

20.9.2 Development Team

- Conducting development activities
- Creating design outputs
- Participating in reviews
- Documentation

20.9.3 Quality Management

- Monitoring development controls
- Conducting audits
- Reviewing documentation

Next Steps: 1. Establish development process 2. Define development phases and gates 3. Implement design review process 4. Establish change management 5. Train development team 6. Monitor development projects

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Chapter 21

Control of Externally Provided Processes, Products and Services

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Version: {{ meta.version }}
Status: Draft
Classification: Internal
Last Update: {{ meta.date }}

21.1 Purpose

This document defines how {{ meta.organization }} controls externally provided processes, products and services to ensure they meet requirements.

21.2 General Requirements (8.4.1)

21.2.1 Scope

Externally provided includes: - Products and services from external providers - Products and services provided directly to customers - Processes or parts of processes provided by external providers - Products and services provided by customers

21.2.2 Control Requirements

{{ meta.organization }} ensures: - Externally provided processes, products and services remain under QMS control - Control on external providers and their outputs is defined - Potential impact on ability to meet customer requirements is considered - Effectiveness of control is determined and applied

21.2.3 Types of Control

Type and extent of control depends on: - Potential impact on conformity of products and services - Effectiveness of control applied by external provider - Ability of organization to apply required control

21.3 External Providers (8.4.1)

21.3.1 Provider Types

{{ meta.organization }} categorizes external providers:

Category	Description	Control Level	Examples
Critical	Direct impact on product quality	High	[TODO]
Important	Indirect impact on quality	Medium	[TODO]
Standard	Low impact	Low	[TODO]

21.3.2 Provider Selection

Selection Criteria: - Ability to meet requirements - Quality management system - Technical competence - Delivery performance - Financial stability - Certifications - References

Selection Process: 1. Identify need 2. Identify potential providers 3. Evaluate providers 4. Select provider 5. Qualify provider 6. Conclude contract

21.4 Provider Qualification (8.4.1)

21.4.1 Qualification Methods

{{ meta.organization }} qualifies providers through: - Assessment of quality capability - Provider audits - Evaluation of samples or prototypes - Review of certificates - Evaluation of delivery performance - Reference checks

21.4.2 Qualification Criteria

Providers must demonstrate: - Quality management system (e.g., ISO 9001 certification) - Technical capabilities - Production capacity - Delivery reliability - Financial stability - Compliance with statutory requirements

Qualification Form:

Criterion	Assessment	Evidence	Status
QMS	[TODO: e.g., 1-5]	[TODO]	[TODO]
Technical Competence	[TODO]	[TODO]	[TODO]
Delivery Performance	[TODO]	[TODO]	[TODO]
Financial Stability	[TODO]	[TODO]	[TODO]

21.5 Provider Performance (8.4.1)

21.5.1 Performance Evaluation

{{ meta.organization }} evaluates provider performance based on: - Quality of delivered products/services - On-time delivery (date and quantity) - Responsiveness - Problem-solving capability - Price-performance ratio - Communication

21.5.2 Performance Indicators

KPIs for Providers:

KPI	Target Value	Measurement Frequency	Actions if Not Achieved
Quality rate	[TODO: e.g., 98%]	Monthly	[TODO]
On-time delivery	[TODO: e.g., 95%]	Monthly	[TODO]
Complaint rate	[TODO: e.g., 2%]	Monthly	[TODO]
Response time	[TODO]	[TODO]	[TODO]

21.5.3 Performance Monitoring

Monitoring Methods: - Incoming inspection - Regular evaluations - Provider audits - Performance reports - Supplier meetings

21.6 Provider Development

21.6.1 Development Measures

For insufficient performance: - Problem analysis with provider - Corrective action plan - Support for improvements - Regular progress reviews - Re-evaluation after improvements

21.6.2 Provider Audits

Audit Program: - **Frequency:** [TODO: e.g., Annually for critical providers] - **Scope:** QMS, production processes, quality control - **Conduct:** [TODO: Internal team or external auditors]

Audit Criteria: - Compliance with requirements - Process control - Quality assurance - Documentation - Continual improvement

21.7 Information for External Providers (8.4.2)

21.7.1 Communication Requirements

{{ meta.organization }} communicates to external providers: - Processes, products and services to be provided - Approval of products, procedures, processes and equipment - Release of products and services - Competence, including required qualifications - Interactions with organization's QMS - Control and monitoring of performance - Verification activities at provider's premises

21.7.2 Specifications and Requirements

Orders/contracts contain: - Product specifications - Quality requirements - Delivery conditions - Inspection requirements - Documentation requirements - Change management - Escalation process

21.8 Verification of Externally Provided Products (8.4.3)

21.8.1 Verification Activities

{{ meta.organization }} verifies through: - Incoming inspection - Review of accompanying documents - Sample inspections - Audits at provider - Monitoring of processes at provider

21.8.2 Incoming Inspection

Inspection scope depends on: - Criticality of product/service - Provider performance - Complexity - Risk

Inspection Criteria: - Conformity with specifications - Completeness - Condition - Documentation

For Non-conformity: 1. Reject or quarantine goods 2. Inform provider 3. Request corrective actions 4. Arrange replacement delivery 5. Document incident

21.9 Provider Register

21.9.1 Approved Providers

{{ meta.organization }} maintains register of approved providers:

Provider	Category	Products/Services	Qualified Since	Last Evaluation	Status
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

21.9.2 Blocked Providers

Providers can be blocked for: - Repeated quality problems - Delivery problems - Non-compliance with requirements - Lack of cooperation

21.10 Responsibilities

21.10.1 Purchasing

- Provider selection and qualification
- Contract management
- Order processing
- Provider performance evaluation

21.10.2 Quality Management

- Definition of quality requirements

- Incoming inspection
- Provider audits
- Monitoring provider performance

21.10.3 Departments

- Specification of requirements
- Technical evaluation
- Support in provider development

Next Steps: 1. Identify all external providers 2. Categorize providers by criticality 3. Establish provider qualification process 4. Implement performance evaluation 5. Conduct regular provider audits 6. Maintain provider register

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Chapter 22

Production and Service Provision

Document-ID: 0440
Owner: {{ meta.owner }}
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Status: Draft
Classification: Internal
Last Update: {{ meta.date }}

22.1 Purpose

This document defines how {{ meta.organization }} implements production and service provision under controlled conditions.

22.2 Controlled Conditions (8.5.1)

22.2.1 Control Requirements

{{ meta.organization }} implements production and service provision under controlled conditions through: - Availability of documented information on product characteristics - Availability of work instructions - Use of suitable equipment - Availability and use of monitoring and measuring devices - Implementation of monitoring and measurement activities - Use of suitable infrastructure and environment - Appointment of competent persons - Validation of processes - Implementation of actions to prevent human error - Implementation of release, delivery and post-delivery activities

22.2.2 Work Instructions

Work instructions available for: - Critical production processes - Complex activities - Quality-critical steps - Safety-relevant activities

Work instructions contain: - Step-by-step guidance - Required materials and tools - Quality criteria - Safety notes - Inspection requirements

22.3 Identification and Traceability (8.5.2)

22.3.1 Identification

{{ meta.organization }} identifies outputs by: - Unique marking - Batch numbers - Serial numbers - Production date - Work order number

Identification Methods: - [TODO: e.g., Labels, barcodes, RFID, markings]

22.3.2 Traceability

Traceability required for: - [TODO: e.g., All products, critical products, regulated products]

Traceable Information: - Raw materials and components (batch, supplier) - Production date and time - Equipment used - Inspections performed - Personnel involved - Customer and delivery address

Traceability System: - [TODO: Describe system, e.g., ERP system, production data capture]

22.4 Property of Customers or External Providers (8.5.3)

22.4.1 Types of Customer Property

Customer property includes: - Materials for processing - Tools and fixtures - Intellectual property - Personal data - Confidential information

22.4.2 Handling Customer Property

{{ meta.organization }} ensures: - Identification upon receipt - Verification and protection - Secure storage - Use only for intended purpose - Return or disposal as agreed

For loss, damage or unsuitable use: 1. Inform customer 2. Document incident 3. Investigate cause 4. Take corrective actions

Customer Property Register:

Property	Customer	Receipt Date	Condition	Location	Status
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

22.5 Preservation (8.5.4)

22.5.1 Preservation Requirements

{{ meta.organization }} preserves outputs during production and service provision: - Identification - Handling - Contamination control - Packaging - Storage - Transmission or transport - Protection

22.5.2 Handling

Handling Requirements: - Appropriate handling methods - Avoidance of damage - Use of suitable equipment - Training of personnel

Handling Instructions for: - [TODO: e.g., Sensitive products, heavy parts, hazardous materials]

22.5.3 Storage

Storage Requirements: - Suitable storage conditions (temperature, humidity) - Protection from damage and deterioration - FIFO/FEFO principle - Regular inventory checks - Separation of different product types

Storage Areas:

Area	Products	Conditions	Responsible
[TODO]	[TODO]	[TODO]	[TODO]

22.5.4 Packaging

Packaging Requirements: - Protection during transport and storage - Compliance with customer requirements - Marking according to regulations - Environmentally friendly materials (if applicable)

22.6 Post-Delivery Activities (8.5.5)

22.6.1 Post-Delivery Activities

{{ meta.organization }} meets requirements for post-delivery activities: - Statutory and regulatory requirements - Potential undesired consequences of products/services - Nature, use and intended lifetime - Customer requirements - Customer feedback

Post-delivery activities include: - Warranty and guarantee - Maintenance and service - Technical support - Spare parts supply - Take-back and recycling - Training and consulting

22.6.2 Warranty and Guarantee

Warranty Conditions: - **Duration:** [TODO: e.g., 12 months, 24 months] - **Scope:** [TODO: What is covered?] - **Exclusions:** [TODO: What is not covered?]

Warranty Handling: 1. Check warranty claim 2. Conduct failure analysis 3. Repair or replacement 4. Documentation 5. Root cause analysis

22.6.3 Customer Service

Customer Service: - Hotline/support - On-site service - Remote maintenance - Training - Spare parts service

Service Level Agreements (SLA): - Response time: [TODO] - Resolution time: [TODO] - Availability: [TODO]

22.7 Control of Changes (8.5.6)

22.7.1 Change Management

{{ meta.organization }} reviews and controls changes for production or service provision: - Changes are documented - Impacts are assessed - Changes are approved - Actions to prevent

adverse impacts are taken - Documented information is retained

22.7.2 Change Process

Steps: 1. Identify need for change 2. Create change request 3. Conduct impact analysis 4. Approve change 5. Implement change 6. Verify change 7. Update documentation 8. Inform affected parties

22.8 Release of Products and Services (8.6)

22.8.1 Release Process

{{ meta.organization }} implements planned arrangements to verify requirements are met: - Release only after satisfactory completion - Documented information on release is retained - Traceability to persons authorizing release

22.8.2 Release Criteria

Products/services released when: - All inspections passed - Specifications met - Documentation complete - Approval granted

Release Authority:

Product Type	Release Authority	Criteria
[TODO]	[TODO]	[TODO]

22.8.3 Release with Deviation

Release despite non-conformity only when: - Customer approves (if applicable) - Authority approves (if applicable) - Deviation documented - Traceability ensured

22.9 Control of Nonconforming Outputs (8.7)

22.9.1 Identification and Control

{{ meta.organization }} ensures nonconforming outputs: - Are identified and controlled - Are not used or delivered unintentionally - Are marked - Are segregated (if practicable)

22.9.2 Dealing with Non-conformity

Actions: - **Correction:** Rework, sorting - **Use under deviation:** With approval - **Release under concession:** With approval - **Rejection:** Scrapping, return

Non-conformity Report:

Field	Description
NC Number	Unique identifier
Date	Detection date
Description	Nature of non-conformity
Quantity	Affected quantity

Field	Description
Cause	Root cause analysis
Action	Action taken
Responsible	Responsible person
Status	Open/Closed

22.10 Responsibilities

22.10.1 Production Manager

- Ensuring controlled conditions
- Monitoring production
- Release of products

22.10.2 Quality Control

- Conducting inspections
- Identifying non-conformities
- Release decisions

22.10.3 Warehouse/Logistics

- Preservation of products
- Handling customer property
- Shipping and delivery

Next Steps: 1. Establish controlled conditions 2. Implement identification and traceability system 3. Define handling and storage requirements 4. Establish release process 5. Implement nonconformity management

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Chapter 23

Monitoring, Measurement, Analysis and Evaluation

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Status: Draft
Classification: Internal
Last Update: {{ meta.date }}

23.1 Purpose

This document defines how {{ meta.organization }} monitors, measures, analyzes and evaluates the performance and effectiveness of the QMS.

23.2 General Requirements (9.1.1)

23.2.1 Monitoring and Measurement Requirements

{{ meta.organization }} determines: - **What** needs to be monitored and measured - **Methods** for monitoring, measurement, analysis and evaluation - **When** monitoring and measurement are performed - **When** results are analyzed and evaluated

23.2.2 Performance Evaluation

{{ meta.organization }} evaluates: - Performance and effectiveness of QMS - Conformity of products and services - Customer satisfaction - Effectiveness of actions for risks and opportunities - Performance of external providers - Need for improvement

23.2.3 Documentation

Documented information as evidence of: - Monitoring and measurement results - Analysis results - Evaluation results

23.3 Customer Satisfaction (9.1.2)

23.3.1 Monitoring Methods

{{ meta.organization }} monitors customer perceptions through: - Customer surveys - Customer feedback and complaints - Customer meetings - Market share analyses - Compliments and awards - Warranty claims - Dealer reports

23.3.2 Customer Surveys

Survey Details: - **Frequency:** [TODO: e.g., Annually, after each project] - **Method:** [TODO: e.g., Online survey, phone interview, personal meeting] - **Sample:** [TODO: e.g., All customers, sample] - **Topics:** Product quality, delivery, service, price-performance, overall satisfaction

Rating Scale: - [TODO: e.g., 1-5, 1-10, Very satisfied to Very dissatisfied]

23.3.3 Customer Feedback

Feedback Channels: - Complaint management - Customer service contacts - Social media - Review platforms - Direct communication

Feedback Evaluation: - Categorization by topics - Trend analysis - Identification of improvement potential

23.3.4 Customer Satisfaction Goals

Goals: - Overall satisfaction: [TODO: e.g., 4.0 of 5.0] - Recommendation rate: [TODO: e.g., 80%] - Complaint rate: [TODO: e.g., 2%] - Repurchase rate: [TODO: e.g., 70%]

23.4 Analysis and Evaluation (9.1.3)

23.4.1 Data Analysis

{{ meta.organization }} analyzes and evaluates data on: - Conformity of products and services - Degree of customer satisfaction - Performance and effectiveness of QMS - Effectiveness of planning - Effectiveness of actions for risks and opportunities - Performance of external providers - Need for improvement

23.4.2 Analysis Methods

Methods Used: - Statistical process control (SPC) - Trend analyses - Pareto analyses - Cause-and-effect diagrams - Correlation analyses - Benchmarking

23.4.3 Performance Indicators (KPIs)

QMS Performance Indicators:

KPI	Target Value	Actual Value	Trend	Actions
Customer satisfaction	[TODO]	[TODO]	[TODO]	[TODO]
On-time delivery	[TODO]	[TODO]	[TODO]	[TODO]
Quality rate	[TODO]	[TODO]	[TODO]	[TODO]

KPI	Target Value	Actual Value	Trend	Actions
Complaint rate	[TODO]	[TODO]	[TODO]	[TODO]
Process efficiency	[TODO]	[TODO]	[TODO]	[TODO]
Audit conformity	[TODO]	[TODO]	[TODO]	[TODO]

23.4.4 Reporting

Reports: - **Monthly Reports:** Operational KPIs - **Quarterly Reports:** QMS performance, trends - **Annual Reports:** Overall assessment, strategic goals

Report Recipients: - Top management - Quality manager - Process owners - Relevant departments

23.5 Process Performance

23.5.1 Process Monitoring

For each process, {{ meta.organization }} monitors: - Process inputs and outputs - Process performance (efficiency, effectiveness) - Compliance with process criteria - Resource utilization - Process risks

Process KPIs:

Process	KPI	Target Value	Measurement Frequency	Responsible
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

23.5.2 Process Evaluation

Evaluation Criteria: - Goal achievement - Efficiency - Effectiveness - Customer satisfaction - Conformity with requirements

23.6 Product Performance

23.6.1 Product Monitoring

{{ meta.organization }} monitors: - Product conformity with specifications - Product quality - Product reliability - Product performance in field - Warranty claims

Product KPIs:

Product	KPI	Target Value	Actual Value	Status
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

23.6.2 Field Performance

Monitoring field performance through: - Warranty and guarantee data - Customer feedback - Service reports - Recall actions (if applicable)

23.7 Improvement Potential

23.7.1 Identification

Improvement potential identified through: - Data analysis - Audit results - Customer feedback - Employee suggestions - Benchmarking - Management review

23.7.2 Prioritization

Prioritization Criteria: - Impact on customer satisfaction - Impact on quality - Cost-benefit ratio - Feasibility - Urgency

23.8 Responsibilities

23.8.1 Quality Manager

- Overall responsibility for monitoring and measurement
- Coordination of data analysis
- Reporting to top management

23.8.2 Process Owners

- Monitoring their processes
- Data collection and analysis
- Implementation of improvement actions

23.8.3 All Employees

- Contributing to data collection
- Reporting problems
- Participating in improvements

Next Steps: 1. Define all parameters to be monitored 2. Establish measurement methods and frequencies 3. Implement data collection systems 4. Conduct regular analyses 5. Report results to relevant parties 6. Identify and prioritize improvements

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Chapter 24

Internal Audit

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24.1 Purpose

This document defines the internal audit program of {{ meta.organization }} to ensure the QMS is conforming, effectively implemented and maintained.

24.2 Audit Program (9.2)

24.2.1 Program Objectives

The audit program ensures: - QMS conforms to organization's own requirements - QMS conforms to ISO 9001:2015 requirements - QMS is effectively implemented and maintained

24.2.2 Program Planning

{{ meta.organization }} plans audits considering: - Importance of processes to be audited - Changes affecting the organization - Results of previous audits - Risks and opportunities

Audit Frequency:

Process/Area	Audit Frequency	Justification
Critical processes	[TODO: e.g., Semi-annually]	High importance
Important processes	[TODO: e.g., Annually]	Medium importance
Supporting processes	[TODO: e.g., Every 2 years]	Low importance

24.2.3 Annual Audit Plan

Audit Plan for [TODO: Year]:

Month	Audit Area	Auditor	Status
January	[TODO]	[TODO]	[TODO]
February	[TODO]	[TODO]	[TODO]
March	[TODO]	[TODO]	[TODO]
[TODO]	[TODO]	[TODO]	[TODO]

24.3 Audit Criteria and Scope (9.2.2)

24.3.1 Audit Criteria

Audits assess conformity with: - ISO 9001:2015 requirements - Organization's own QMS requirements - Process documentation - Work instructions - Statutory and regulatory requirements

24.3.2 Audit Scope

Audits cover: - All QMS processes - All locations (if applicable) - All relevant departments - Documented information - Records

Audit Scope per Audit: - [TODO: Define typical scope]

24.4 Auditor Selection (9.2.2)

24.4.1 Auditor Qualification

Auditors must: - Be independent from area being audited - Be objective and impartial - Be competent in audit methods - Have knowledge of ISO 9001 - Have knowledge of audited processes

Auditor Qualifications: - Training: [TODO: e.g., ISO 9001 Lead Auditor course] - Experience: [TODO: e.g., Minimum 3 audits as co-auditor] - Competence: [TODO: Assessment criteria]

24.4.2 Auditor Register

Qualified Auditors:

Name	Qualification	Certificate	Experience	Status
[TODO]	[TODO]	[TODO]	[TODO]	Active

24.4.3 Auditor Independence

Auditors must not: - Audit their own work - Audit areas for which they are responsible - Have personal interests in audited area

24.5 Audit Conduct

24.5.1 Audit Preparation

Steps: 1. Create audit plan 2. Assemble audit team 3. Inform audited areas 4. Review relevant documentation 5. Create audit checklist

Audit Announcement: - Timing: [TODO: e.g., 2 weeks before audit] - Method: [TODO: e.g., Email, meeting] - Content: Date, scope, auditors, schedule

24.5.2 Opening Meeting

Agenda: - Introduction of audit team - Confirmation of scope and objectives - Explanation of audit methods - Confirmation of schedule - Clarification of questions

24.5.3 Audit Execution

Audit Methods: - Interviews with personnel - Observation of activities - Review of documents - Review of records - Sample checks

Audit Checklist: - [TODO: Create standardized checklist based on ISO 9001 requirements]

24.5.4 Findings

Types of Findings: - **Conformity:** Requirements met - **Non-conformity (Major):** Serious non-conformity - **Non-conformity (Minor):** Minor non-conformity - **Improvement Potential:** Recommendation for improvement

Documentation of Findings: - Description of finding - Affected area/process - Reference to requirement - Objective evidence - Classification

24.5.5 Closing Meeting

Agenda: - Presentation of audit results - Explanation of findings - Discussion of non-conformities - Agreement on corrective actions - Timeline for actions - Acknowledgment

24.6 Audit Report (9.2.2)

24.6.1 Report Content

Audit report contains: - Audit date and location - Audit scope and criteria - Audit team - Audited areas and persons - Summary of results - Findings (conformities and non-conformities) - Improvement potentials - Conclusions - Distribution list

24.6.2 Report Distribution

Report distributed to: - Audited areas - Quality manager - Top management - Relevant process owners

Distribution Timing: - [TODO: e.g., Within 2 weeks after audit]

24.7 Corrective Actions (9.2.2)

24.7.1 Action Planning

For non-conformities: 1. Conduct root cause analysis 2. Define corrective actions 3. Assign responsibilities 4. Set timeline 5. Approve actions

Corrective Action Plan:

Non-conformity	Cause	Action	Responsible	Due Date	Status
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

24.7.2 Action Follow-up

{{ meta.organization }} ensures: - Actions are implemented timely - Effectiveness is verified - Documentation is retained

Follow-up through: - Regular status checks - Follow-up audits (for serious non-conformities) - Review in management review

24.8 Audit Records

24.8.1 Documented Information

Records include: - Audit program - Audit plans - Audit checklists - Audit reports - Corrective action plans - Evidence of action implementation - Auditor qualifications

24.8.2 Retention

Retention Period: - [TODO: e.g., Minimum 3 years or according to statutory requirements]

24.9 Audit Program Evaluation

24.9.1 Effectiveness Evaluation

{{ meta.organization }} evaluates effectiveness of audit program through: - Achievement of program objectives - Quality of audits - Competence of auditors - Timely conduct - Effectiveness of corrective actions

Evaluation conducted: - [TODO: e.g., Annually in management review]

24.9.2 Program Improvement

Improvements based on: - Feedback from audited areas - Auditor feedback - Changes in organization - New requirements - Lessons learned

24.10 Responsibilities

24.10.1 Quality Manager

- Overall responsibility for audit program

- Planning and coordination of audits
- Auditor selection and qualification
- Monitoring corrective actions

24.10.2 Auditors

- Conducting audits
- Creating audit reports
- Objective and impartial assessment

24.10.3 Audited Areas

- Providing information
- Supporting audits
- Implementing corrective actions

24.10.4 Top Management

- Providing resources
- Reviewing audit results
- Approving actions

Next Steps: 1. Create annual audit plan 2. Qualify auditors 3. Develop audit checklists 4. Conduct audits according to plan 5. Follow up corrective actions 6. Evaluate program effectiveness

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Chapter 25

Management Review

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25.1 Purpose

This document defines how {{ meta.organization }} conducts regular management reviews to ensure continuing suitability, adequacy and effectiveness of the QMS.

25.2 General Requirements (9.3)

25.2.1 Review Frequency

{{ meta.organization }} conducts management reviews: - **Regularly:** [TODO: e.g., At least annually, quarterly] - **As needed:** For significant changes or events

Planned Reviews for [TODO: Year]:

Quarter	Date	Participants	Status
Q1	[TODO]	[TODO]	[TODO]
Q2	[TODO]	[TODO]	[TODO]
Q3	[TODO]	[TODO]	[TODO]
Q4	[TODO]	[TODO]	[TODO]

25.2.2 Participants

Required Participants: - Top management - Quality manager - Process owners - Other relevant managers

Optional Participants: - External consultants - Customer representatives (if applicable) - Supplier representatives (if applicable)

25.3 Management Review Inputs (9.3.2)

25.3.1 Required Inputs

Management review considers:

25.3.1.1 1. Status of Actions from Previous Reviews

- Open actions and their status
- Effectiveness of implemented actions
- Reasons for delays

25.3.1.2 2. Changes in External and Internal Issues

- Market changes
- Competitive situation
- Technological developments
- Organizational changes
- Strategic direction

25.3.1.3 3. Information on QMS Performance

a) Customer Satisfaction: - Customer survey results - Customer feedback and complaints - Customer satisfaction trends - Net Promoter Score (if applicable)

b) Extent to Which Quality Objectives Have Been Met:

Quality Objective	Target Value	Actual Value	Achievement	Trend
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

c) Process Performance and Product Conformity: - Process KPIs - Product quality metrics - Scrap rates - Rework rates - On-time delivery

d) Non-conformities and Corrective Actions: - Number and type of non-conformities - Status of corrective actions - Effectiveness of actions - Recurring problems

e) Monitoring and Measurement Results: - Process monitoring results - Product inspection results - Calibration status - Measurement accuracy

f) Audit Results: - Internal audit results - External audit results (certification, customer) - Findings and trends - Conformity level

g) Performance of External Providers: - Supplier evaluations - Quality of delivered products/services - On-time delivery - Problems and improvements

25.3.1.4 4. Adequacy of Resources

- Personnel resources
- Infrastructure
- Process environment
- Monitoring and measurement resources
- Organizational knowledge

25.3.1.5 5. Effectiveness of Actions Taken for Risks and Opportunities

- Identified risks and opportunities
- Implemented actions
- Effectiveness of actions
- New risks and opportunities

25.3.1.6 6. Opportunities for Improvement

- Identified improvement potentials
- Employee suggestions
- Benchmarking results
- Innovation opportunities

25.4 Management Review Outputs (9.3.3)

25.4.1 Required Outputs

Management review must include decisions and actions on:

25.4.1.1 1. Opportunities for Improvement

- Identified improvement areas
- Prioritization of improvements
- Resource allocation
- Timelines

25.4.1.2 2. Need for Changes to QMS

- Process changes
- Documentation changes
- Structural changes
- System expansions

25.4.1.3 3. Resource Needs

- Additional personnel
- Training needs
- Infrastructure investments
- Technology upgrades
- Budget

25.5 Review Process

25.5.1 Preparation

Preparation Steps: 1. Set date and invite participants 2. Collect and prepare input data 3. Prepare presentations 4. Create and distribute agenda 5. Provide relevant documents

Agenda Template: 1. Opening and objectives 2. Review of agenda 3. Status of actions from previous review 4. Presentation of inputs (see 9.3.2) 5. Discussion and evaluation 6. Decisions and actions 7. Summary and closing

25.5.2 Conduct

During Review: - Presentation of all inputs - Discussion of trends and patterns - Identification of problems and opportunities - Decision making - Determination of actions - Assignment of responsibilities - Setting of deadlines

25.5.3 Documentation

Review Minutes Contain: - Date and participants - Inputs reviewed - Discussion points - Decisions made - Agreed actions with responsibilities and deadlines - Signatures

Minutes Template:

Topic	Discussion	Decision	Action	Responsible	Due Date
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

25.6 Action Follow-up

25.6.1 Action Plan

For each action: - Clear description - Responsible person - Target date - Required resources - Success criteria

25.6.2 Monitoring

{{ meta.organization }} monitors: - Progress of action implementation - Compliance with deadlines - Effectiveness of implemented actions - Need for adjustments

Status Reports: - [TODO: e.g., Monthly, quarterly]

25.7 Communication

25.7.1 Internal Communication

Results communicated to: - All employees (summary) - Process owners (relevant parts) - Quality team (complete)

Communication Methods: - [TODO: e.g., Email, intranet, meetings, notices]

25.7.2 External Communication

If relevant, communicated to: - Customers (for significant changes) - Suppliers (for relevant decisions) - Certification body (for system changes)

25.8 Review Metrics

25.8.1 Effectiveness Indicators

Effectiveness of management review measured by: - Number of improvements identified - Implementation rate of actions - Improvement in QMS performance - Achievement of quality objectives - Customer satisfaction trends

25.8.2 Continual Improvement

Improvement of review process through: - Feedback from participants - Assessment of data quality - Optimization of preparation - Improvement of presentations - More efficient conduct

25.9 Responsibilities

25.9.1 Top Management

- Leading management review
- Decision making
- Providing resources
- Approving actions

25.9.2 Quality Manager

- Organization and coordination
- Collection and preparation of inputs
- Creating agenda
- Recording minutes
- Following up actions

25.9.3 Process Owners

- Providing process data
- Presenting their areas
- Implementing actions
- Reporting progress

Next Steps: 1. Plan next management review 2. Collect and prepare input data 3. Create agenda and invite participants 4. Conduct review 5. Document results 6. Communicate decisions 7. Follow up action implementation

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Chapter 26

Improvement

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26.1 Purpose

This document defines how {{ meta.organization }} implements continual improvement to enhance customer satisfaction and improve QMS performance.

26.2 General Requirements (10.1)

26.2.1 Improvement Commitment

{{ meta.organization }} continually improves: - Suitability, adequacy and effectiveness of QMS - Products and services - Processes - Customer satisfaction

26.2.2 Improvement Sources

Improvements identified through: - Quality policy and objectives - Audit results - Data analysis - Corrective actions - Management review - Employee suggestions - Customer feedback - Benchmarking - Innovation

26.3 Improvement Methods

26.3.1 Continual Improvement (Kaizen)

Principles: - Small, incremental improvements - Involvement of all employees - Focus on process improvement - Data-based decisions

Implementation: - Regular improvement workshops - Employee suggestion system - Process optimization teams - Lessons learned sessions

26.3.2 Breakthrough Improvements

For larger improvements: - Project-based approach - Dedicated resources - Structured project management - Measurement of results

26.3.3 Improvement Tools

{{ meta.organization }} uses: - PDCA cycle (Plan-Do-Check-Act) - Six Sigma / DMAIC - Lean Management - 5S Method - Value stream analysis - Cause-and-effect analysis - Pareto analysis - Brainstorming and creativity techniques

26.4 Employee Suggestion System

26.4.1 Suggestion Process

Steps: 1. Employee identifies improvement potential 2. Suggestion is submitted (form/system) 3. Suggestion is reviewed and evaluated 4. Decision on implementation 5. Implementation (if approved) 6. Feedback to employee 7. Recognition/reward

Suggestion Form:

Field	Description
Suggestion Number	Unique identifier
Date	Submission date
Employee	Name of submitter
Area	Affected area/process
Problem	Description of current problem
Suggestion	Described improvement
Benefit	Expected benefit
Effort	Estimated effort

26.4.2 Evaluation Criteria

Suggestions evaluated by: - Impact on quality - Impact on customer satisfaction - Cost-benefit ratio - Feasibility - Innovation level

26.4.3 Recognition

Recognition System: - [TODO: e.g., Bonuses, awards, public recognition] - [TODO: Define criteria for rewards]

26.5 Improvement Projects

26.5.1 Project Selection

Projects selected based on: - Strategic importance - Impact on customer satisfaction - Cost-benefit ratio - Available resources - Urgency

26.5.2 Project Management

Project Phases: 1. **Initiation:** Define project goal and scope 2. **Planning:** Detailed planning, resources, schedule 3. **Execution:** Implementation of actions 4. **Monitoring:** Progress control 5. **Closure:** Results evaluation, documentation

Project Documentation: - Project charter - Project plan - Status reports - Final report

26.5.3 Project Teams

Team Composition: - Project leader - Subject matter experts - Process owners - Quality management - Other relevant employees

26.6 Improvement Goals

26.6.1 Goal Setting

Improvement Goals for [TODO: Year]:

Area	Goal	Measure	Target Value	Responsible
Customer satisfaction	[TODO]	[TODO]	[TODO]	[TODO]
Process efficiency	[TODO]	[TODO]	[TODO]	[TODO]
Quality rate	[TODO]	[TODO]	[TODO]	[TODO]
On-time delivery	[TODO]	[TODO]	[TODO]	[TODO]

26.6.2 Goal Tracking

Monitoring: - Regular status reports - Quarterly review - Adjustment as needed - Reporting in management review

26.7 Improvement Culture

26.7.1 Culture Development

{{ meta.organization }} promotes improvement culture through: - Leadership role modeling - Open communication - Error tolerance and learning culture - Recognition of improvements - Training and empowerment - Providing resources

26.7.2 Training

Training Topics: - Improvement methods and tools - Problem-solving techniques - Process thinking - Data analysis - Project management

26.7.3 Communication

Improvements communicated through: - Regular meetings - Newsletter - Intranet - Notice boards - Success stories

26.8 Improvement Measurement

26.8.1 Performance Indicators

KPIs for Improvement:

KPI	Description	Target Value	Actual Value
Number of improvement suggestions	Per employee/year	[TODO]	[TODO]
Implementation rate	% of implemented suggestions	[TODO]	[TODO]
Improvement projects	Number of completed projects	[TODO]	[TODO]
Savings	Through improvements	[TODO]	[TODO]
Quality improvement	Reduction in error rate	[TODO]	[TODO]

26.8.2 Success Measurement

Success of improvements measured by: - Goal achievement - Cost-benefit analysis - Customer satisfaction - Process performance - Employee satisfaction

26.9 Documentation

26.9.1 Improvement Register

Register contains:

ID	Date	Source	Description	Status	Responsible	Result
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

26.9.2 Lessons Learned

Documentation of: - Successful improvements - Failed attempts - Gained insights - Best practices

Knowledge Management: - Central repository - Accessible to all employees - Regular updates - Use for future projects

26.10 Responsibilities

26.10.1 Top Management

- Promoting improvement culture
- Providing resources
- Approving improvement projects
- Recognizing successes

26.10.2 Quality Manager

- Coordinating improvement activities
- Managing suggestion system
- Monitoring improvement projects
- Reporting progress

26.10.3 All Employees

- Identifying improvement potential
- Submitting suggestions
- Participating in improvement projects
- Implementing improvements

Next Steps: 1. Establish improvement culture 2. Implement suggestion system 3. Define improvement goals 4. Start improvement projects 5. Train employees in improvement methods 6. Measure and communicate successes

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Chapter 27

Nonconformity and Corrective Action

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27.1 Purpose

This document defines how {{ meta.organization }} deals with nonconformities and implements corrective actions to prevent recurrence.

27.2 Reaction to Nonconformity (10.2.1)

27.2.1 Identification

Nonconformities identified through: - Incoming inspection - Production inspection - Final inspection - Customer complaints - Internal audits - External audits - Process monitoring - Employee observations

27.2.2 Immediate Actions

When nonconformity occurs: 1. **React:** Take immediate actions to control and correct 2. **Evaluate:** Assess consequences 3. **Act:** Take actions to: - Correct the nonconformity - Deal with consequences - Prevent use/delivery

27.2.3 Nonconformity Report

Report contains:

Field	Description
NC Number	Unique identifier
Date	Detection date
Reporter	Person who detected NC
Area	Affected area/process
Description	Detailed description of NC
Category	[TODO: e.g., Product, Process, System]
Severity	[TODO: e.g., Critical, Major, Minor]
Affected Quantity	Number/extent
Immediate Action	Immediate action taken
Status	Open/In Progress/Closed

27.3 Root Cause Analysis (10.2.1)

27.3.1 Analysis Methods

{{ meta.organization }} uses: - 5-Why Method - Ishikawa Diagram (Fishbone Diagram) - Failure-Cause Analysis - Pareto Analysis - Fault Tree Analysis - 8D Method (for complex problems)

27.3.2 5-Why Method

Example: 1. Why did NC occur? [TODO: Answer] 2. Why? [TODO: Answer] 3. Why? [TODO: Answer] 4. Why? [TODO: Answer] 5. Why? [TODO: Root cause]

27.3.3 Ishikawa Diagram

Categories: - Man (Personnel) - Machine (Equipment) - Material - Method (Process) - Measurement - Environment (Milieu)

27.3.4 Cause Documentation

Document: - Identified causes - Analysis method used - Persons involved - Date of analysis - Root cause(s)

27.4 Corrective Actions (10.2.1)

27.4.1 Action Planning

Corrective actions must: - Address root cause - Be appropriate for effects - Prevent recurrence - Be feasible - Be measurable

Action Plan:

Action	Responsible	Due Date	Resources	Status
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

27.4.2 Action Types

Distinction: - **Correction:** Elimination of detected NC (immediate action) - **Corrective Action:** Elimination of cause to prevent recurrence

Examples of Corrective Actions: - Process changes - Training - Change of work instructions - Equipment improvement - Change of specifications - Enhanced monitoring

27.5 Implementation of Actions (10.2.1)

27.5.1 Implementation

Steps: 1. Approve actions 2. Provide resources 3. Assign responsibilities 4. Set timeline 5. Implement actions 6. Update documentation 7. Inform affected parties

27.5.2 Monitoring

{{ meta.organization }} monitors: - Progress of implementation - Compliance with deadlines - Availability of resources - Emerging problems

Status Reports: - [TODO: e.g., Weekly, monthly]

27.6 Effectiveness Evaluation (10.2.1)

27.6.1 Evaluation Methods

Effectiveness evaluated through: - Monitoring after implementation - Checking if NC recurs - Measuring relevant KPIs - Audits - Process monitoring

Evaluation Period: - [TODO: e.g., 3 months after implementation]

27.6.2 Evaluation Criteria

Action is effective when: - NC does not recur - Root cause is eliminated - Process performance is improved - Goals are achieved

For ineffective actions: 1. Repeat root cause analysis 2. Develop alternative actions 3. Implement new actions 4. Re-evaluate

27.7 Update of Risks and Opportunities (10.2.1)

27.7.1 Risk Assessment

After nonconformity: - Update risk assessment - Identify new risks - Adjust risk treatment - Implement preventive actions

27.7.2 Opportunity Identification

Nonconformities can reveal opportunities for: - Process improvements - Product improvements - Cost reduction - Efficiency increase

27.8 Changes to QMS (10.2.1)

27.8.1 System Changes

If necessary, {{ meta.organization }} changes: - Processes - Procedures - Work instructions - Forms - Training content - Resources

Change Process: 1. Identify need for change 2. Plan change 3. Approve change 4. Implement change 5. Update documentation 6. Train affected parties 7. Verify change

27.9 Documented Information (10.2.2)

27.9.1 Required Records

{{ meta.organization }} retains documented information on: - Nature of nonconformities - Actions taken - Results of corrective actions - Root cause analyses - Effectiveness evaluations

27.9.2 Retention

Retention Period: - [TODO: e.g., Minimum 5 years or according to statutory requirements]

Storage Location: - [TODO: e.g., Quality management system, document management]

27.10 Nonconformity Register

27.10.1 Register Content

Register contains all nonconformities:

NC No	Date	Area	Description	Cause	Action	Status	Effectiveness
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

27.10.2 Evaluation

Regular Evaluation: - Number of NCs per area - Most frequent NC types - Trends - Recurring problems - Effectiveness of actions

Evaluation Frequency: - [TODO: e.g., Monthly, quarterly]

27.11 Escalation

27.11.1 Escalation Criteria

Escalation required for: - Critical nonconformities - Repeated nonconformities - Nonconformities with high impact - Delays in action implementation - Ineffective actions

27.11.2 Escalation Process

Escalation Levels: 1. **Level 1:** Process owner 2. **Level 2:** Quality manager 3. **Level 3:** Top management

Escalation Timeframe: - [TODO: e.g., After 2 weeks without resolution]

27.12 Communication

27.12.1 Internal Communication

Nonconformities communicated to: - Affected areas - Process owners - Quality management - Top management (for critical NCs)

27.12.2 External Communication

If necessary, communicated to: - Customers (for product NCs) - Suppliers (for material NCs) - Authorities (for regulatory NCs) - Certification body (for system NCs)

27.13 Responsibilities

27.13.1 Quality Manager

- Overall responsibility for NC management
- Monitoring corrective actions
- Effectiveness evaluation
- Reporting

27.13.2 Process Owners

- Root cause analysis in their area
- Development of corrective actions
- Implementation of actions
- Documentation

27.13.3 All Employees

- Reporting nonconformities
- Participating in root cause analysis
- Implementing actions
- Complying with changed processes

Next Steps: 1. Establish NC reporting process 2. Train employees in root cause analysis 3. Implement NC register 4. Define escalation process 5. Monitor effectiveness of actions 6. Evaluate NCs regularly

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Chapter 28

Appendix: Process Map

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28.1 Purpose

This appendix presents the process map of {{ meta.organization }} and describes the main processes of the QMS.

28.2 Process Map

28.2.1 Process Overview

Process Structure:

MANAGEMENT PROCESSES

- Strategic Planning
- Management Review
- Quality Management
- Risk Management

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CORE PROCESSES

- Sales and Marketing
- Product Development
- Procurement
- Production/Service Provision

- Delivery and Customer Service

↓

SUPPORT PROCESSES

- Human Resources Management
- IT and Infrastructure
- Document Management
- Internal Audits
- Maintenance

28.2.2 Process Types

Management Processes: - Direct and control the organization - Define strategy and objectives - Monitor performance

Core Processes: - Value-adding processes - Directly customer-oriented - Generate products/services

Support Processes: - Provide resources - Support core processes - Enable process execution

28.3 Process Descriptions

28.3.1 Management Processes

28.3.1.1 M1: Strategic Planning

- **Purpose:** Establishing strategic direction
- **Inputs:** Market analyses, customer needs, internal capabilities
- **Activities:** Strategy development, goal setting, resource planning
- **Outputs:** Corporate strategy, quality objectives, budgets
- **Responsible:** Top management
- **KPIs:** Goal achievement, strategy implementation

28.3.1.2 M2: Management Review

- **Purpose:** Evaluating QMS effectiveness
- **Inputs:** QMS performance data, audit results, customer feedback
- **Activities:** Data analysis, evaluation, decision making
- **Outputs:** Improvement actions, resource decisions
- **Responsible:** Top management
- **KPIs:** Number of improvement actions, implementation rate

28.3.1.3 M3: Quality Management

- **Purpose:** Controlling and improving QMS
- **Inputs:** QMS requirements, process data
- **Activities:** QMS planning, monitoring, improvement
- **Outputs:** QMS documentation, quality reports

- **Responsible:** Quality manager
- **KPIs:** Audit conformity, document currency

28.3.1.4 M4: Risk Management

- **Purpose:** Identifying and treating risks and opportunities
- **Inputs:** Process information, external/internal issues
- **Activities:** Risk identification, assessment, treatment
- **Outputs:** Risk register, action plans
- **Responsible:** Quality manager
- **KPIs:** Number of identified risks, action effectiveness

28.3.2 Core Processes

28.3.2.1 K1: Sales and Marketing

- **Purpose:** Customer acquisition and retention
- **Inputs:** Market information, customer needs
- **Activities:** Marketing, sales, quotation preparation
- **Outputs:** Orders, customer contracts
- **Responsible:** Sales manager
- **KPIs:** Revenue, new customer rate, customer satisfaction

28.3.2.2 K2: Product Development

- **Purpose:** Developing new products/services
- **Inputs:** Customer requirements, market trends
- **Activities:** Conception, design, development, validation
- **Outputs:** New products/services, specifications
- **Responsible:** Development manager
- **KPIs:** Time-to-market, development costs, product success

28.3.2.3 K3: Procurement

- **Purpose:** Providing materials and services
- **Inputs:** Requirement notifications, specifications
- **Activities:** Supplier selection, ordering, incoming inspection
- **Outputs:** Materials, services
- **Responsible:** Purchasing manager
- **KPIs:** Supplier evaluation, on-time delivery, quality rate

28.3.2.4 K4: Production/Service Provision

- **Purpose:** Manufacturing products/providing services
- **Inputs:** Orders, materials, specifications
- **Activities:** Production, quality inspection, packaging
- **Outputs:** Finished products/provided services
- **Responsible:** Production manager
- **KPIs:** Productivity, quality rate, lead time

28.3.2.5 K5: Delivery and Customer Service

- **Purpose:** Delivery to customers and after-sales service
- **Inputs:** Finished products, customer orders
- **Activities:** Shipping, installation, maintenance, support
- **Outputs:** Delivered products, satisfied customers
- **Responsible:** Logistics manager
- **KPIs:** On-time delivery, service quality, customer satisfaction

28.3.3 Support Processes

28.3.3.1 U1: Human Resources Management

- **Purpose:** Providing competent employees
- **Inputs:** Personnel needs, competence requirements
- **Activities:** Recruitment, training, performance evaluation
- **Outputs:** Qualified employees
- **Responsible:** HR manager
- **KPIs:** Employee satisfaction, turnover rate, training hours

28.3.3.2 U2: IT and Infrastructure

- **Purpose:** Providing IT systems and infrastructure
- **Inputs:** IT requirements, infrastructure needs
- **Activities:** IT support, system maintenance, infrastructure management
- **Outputs:** Functioning IT systems, infrastructure
- **Responsible:** IT manager
- **KPIs:** System availability, response time, downtime

28.3.3.3 U3: Document Management

- **Purpose:** Controlling documented information
- **Inputs:** Documents, records
- **Activities:** Document creation, release, distribution, archiving
- **Outputs:** Controlled documents
- **Responsible:** Document coordinator
- **KPIs:** Document currency, access time

28.3.3.4 U4: Internal Audits

- **Purpose:** Verifying QMS conformity
- **Inputs:** Audit program, QMS requirements
- **Activities:** Audit planning, execution, reporting
- **Outputs:** Audit reports, corrective actions
- **Responsible:** Quality manager
- **KPIs:** Audit coverage, findings, action implementation

28.3.3.5 U5: Maintenance

- **Purpose:** Maintaining equipment operability
- **Inputs:** Maintenance plans, fault reports

- **Activities:** Preventive maintenance, repairs
- **Outputs:** Functioning equipment
- **Responsible:** Maintenance manager
- **KPIs:** Equipment availability, downtime, maintenance costs

28.4 Process Interactions

28.4.1 Interfaces

Important Interfaces:

From Process	To Process	Handover
Sales	Production	Customer order
Procurement	Production	Materials
Production	Delivery	Finished products
Quality Management	All Processes	QMS requirements
HR Management	All Processes	Qualified employees

28.4.2 Process Flow

Main Process Flow: 1. Sales receives customer inquiry 2. Quotation created and order won 3. Procurement obtains materials 4. Production manufactures product 5. Quality inspection conducted 6. Delivery to customer 7. Customer service as needed

28.5 Process Responsibilities

28.5.1 RACI Matrix

Responsibilities:

Process	Responsible (R)	Accountable (A)	Consulted (C)	Informed (I)
Strategic Planning	Top Management	CEO	All Department Managers	All Employees
Sales	Sales Manager	CEO	Marketing, Production	All
Production	Production Manager	CEO	Quality, Procurement	Sales
[TODO]	[TODO]	[TODO]	[TODO]	[TODO]

28.6 Process Documentation

28.6.1 Document Hierarchy

For each process: - **Level 1:** Process description (this document) - **Level 2:** Procedures - **Level 3:** Work instructions - **Level 4:** Forms and records

28.6.2 Document References

Process Documents: - [TODO: List relevant procedures] - [TODO: List relevant work instructions]

Note: This process map is a living document and will be updated as needed.

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Chapter 29

Appendix: Forms and Templates

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29.1 Purpose

This appendix contains an overview of all forms and templates used in the QMS of {{ meta.organization }}.

29.2 Form Directory

29.2.1 Management Processes

Strategic Planning: - FORM-M-001: Strategy Planning Template - FORM-M-002: Quality Objectives Form - FORM-M-003: Resource Planning Form

Management Review: - FORM-M-010: Management Review Agenda - FORM-M-011: Management Review Minutes - FORM-M-012: Action Plan from Management Review

Risk Management: - FORM-M-020: Risk Identification Form - FORM-M-021: Risk Assessment Matrix - FORM-M-022: Risk Treatment Plan

29.2.2 Core Processes

Sales and Marketing: - FORM-K-001: Customer Inquiry Form - FORM-K-002: Quotation Template - FORM-K-003: Order Confirmation - FORM-K-004: Customer Visit Report - FORM-K-005: Customer Satisfaction Survey

Product Development: - FORM-K-010: Development Order - FORM-K-011: Requirements

Specification - FORM-K-012: Design Review Minutes - FORM-K-013: Verification Report - FORM-K-014: Validation Report - FORM-K-015: Change Request

Procurement: - FORM-K-020: Purchase Requisition - FORM-K-021: Purchase Order - FORM-K-022: Supplier Evaluation Form - FORM-K-023: Supplier Audit Report - FORM-K-024: Incoming Inspection Report

Production/Service Provision: - FORM-K-030: Production Order - FORM-K-031: Inspection Protocol - FORM-K-032: Nonconformity Report - FORM-K-033: Release Certificate - FORM-K-034: Traceability Protocol

Delivery and Customer Service: - FORM-K-040: Delivery Note - FORM-K-041: Shipping Protocol - FORM-K-042: Installation Report - FORM-K-043: Maintenance Report - FORM-K-044: Service Request - FORM-K-045: Warranty Claim

29.2.3 Support Processes

Human Resources Management: - FORM-U-001: Job Description - FORM-U-002: Competence Matrix - FORM-U-003: Training Plan - FORM-U-004: Training Record - FORM-U-005: Employee Meeting Minutes - FORM-U-006: Performance Appraisal

Document Management: - FORM-U-010: Document Release Form - FORM-U-011: Document Change Request - FORM-U-012: Document Register - FORM-U-013: Records Register

Internal Audits: - FORM-U-020: Annual Audit Plan - FORM-U-021: Audit Plan (single audit) - FORM-U-022: Audit Checklist - FORM-U-023: Audit Report - FORM-U-024: Corrective Action Plan

Maintenance: - FORM-U-030: Maintenance Plan - FORM-U-031: Maintenance Protocol - FORM-U-032: Repair Order - FORM-U-033: Calibration Protocol

29.2.4 Quality Management

General: - FORM-Q-001: Improvement Suggestion - FORM-Q-002: Corrective Action Form - FORM-Q-003: Root Cause Analysis (5-Why) - FORM-Q-004: Ishikawa Diagram Template - FORM-Q-005: 8D Report

Monitoring and Measurement: - FORM-Q-010: KPI Dashboard - FORM-Q-011: Process Performance Report - FORM-Q-012: Quality Report (monthly) - FORM-Q-013: Quality Report (annual)

29.3 Form Templates

29.3.1 Example: Nonconformity Report

```
          NONCONFORMITY REPORT (FORM-K-032)


NC Number: _____________  Date: _____________

Reporter: ____________________  Department: _____________
```

Affected Area/Process: _____

Category: Product Process System Other

Severity: Critical Major Minor

Description of Nonconformity:
_____
_____
_____

Affected Quantity/Extent: _____

Immediate Action:
_____
_____

Performed by: _____ Date: _____

ROOT CAUSE ANALYSIS

Analysis Method: 5-Why Ishikawa Other: _____

Identified Root Cause(s):
_____
_____

Analyzed by: _____ Date: _____

CORRECTIVE ACTIONS

Action 1: _____
Responsible: _____ Due Date: _____

Action 2: _____
Responsible: _____ Due Date: _____

Approved by: _____ Date: _____

EFFECTIVENESS EVALUATION

Evaluation Date: _____

Actions Effective: Yes No

Comments: _____
_____

Evaluated by: _____ Date: _____

Status: Open In Progress Closed

29.3.2 Example: Audit Report

AUDIT REPORT (FORM-U-023)

Audit No: _____ Audit Date: _____

Audit Type: Internal Audit External Audit

Audit Scope: _____

Audit Criteria: ISO 9001:2015, QMS Documentation

Audit Team:
Lead Auditor: _____
Co-Auditor(s): _____

Audited Areas/Processes:
_____

Persons Present:
_____

AUDIT RESULTS

Summary:
_____
_____

Conformities:
_____
_____

```
Non-conformities (Major):
1. _____________________________________________________
   Reference: _____________________________________________

Non-conformities (Minor):
1. _____________________________________________________
   Reference: _____________________________________________

Improvement Potentials:
1. _____________________________________________________
2. _____________________________________________________

Conclusion:
_____________________________________________________________
_____________________________________________________________

Lead Auditor Signature: ____________  Date: __________

Distribution:   Audited Area    QM    Top Management
```

29.4 Form Usage

29.4.1 Completion Instructions

General Rules: - Complete all mandatory fields - Fill out legibly and completely - Date in format DD.MM.YYYY - Signatures where required - Distribute copies to relevant persons

29.4.2 Form Release

Before Use: - Form must be approved - Use current version - Remove obsolete versions

29.4.3 Form Retention

Completed Forms: - Retain according to retention periods - Store securely - Accessible to authorized persons - Protect from unauthorized access

29.5 Digital Forms

29.5.1 Electronic Forms

If applicable: - **System:** [TODO: e.g., Document management system, ERP system] - **Access:** [TODO: How to access electronic forms] - **Workflow:** [TODO: Electronic approval workflow]

29.5.2 Benefits

Electronic forms offer: - Automatic version control - Electronic approval - Easy search and retrieval - Automatic archiving - Reduced paper consumption

29.6 Form Updates

29.6.1 Review

Forms reviewed: - [TODO: e.g., Annually or as needed] - When processes change - When requirements change - After audits

29.6.2 Change Process

For form changes: 1. Identify need for change 2. Revise form 3. Review and approval 4. Update version number 5. Release new version 6. Withdraw old version 7. Inform users

---

Note: All forms are available in the document management system.

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Chapter 30

Appendix: Terms and Abbreviations

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30.1 Purpose

This appendix defines important terms and abbreviations used in the quality management system of {{ meta.organization }}.

30.2 Term Definitions

30.2.1 A

Adequacy Extent to which established activities are realized and planned results achieved.

Audit Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

Audit Criteria Set of policies, procedures or requirements used as a reference.

Audit Evidence Records, statements of fact or other information relevant to audit criteria and verifiable.

30.2.2 C

Characteristic Distinguishing feature.

Competence Ability to apply knowledge and skills to achieve intended results.

Conformity Fulfillment of a requirement.

Continual Improvement Recurring activity to enhance performance.

Correction Action to eliminate a detected nonconformity.

Corrective Action Action to eliminate the cause of a nonconformity and to prevent recurrence.

Customer Person or organization that could or does receive a product or service that is intended for or required by this person or organization.

Customer Satisfaction Customer's perception of the degree to which the customer's expectations have been fulfilled.

30.2.3 D

Documented Information Information required to be controlled and maintained by an organization and the medium on which it is contained.

30.2.4 E

Effectiveness Extent to which planned activities are realized and planned results achieved.

Efficiency Relationship between the result achieved and the resources used.

External Provider External provider, supplier, service provider, contractor or producer that provides a product or service.

30.2.5 I

Infrastructure System of facilities, equipment and services needed for the operation of an organization.

Interested Party Person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity.

30.2.6 M

Management Review Review by top management to ensure continuing suitability, adequacy, effectiveness and alignment of the QMS.

Measurement Process to determine a value.

Monitoring Determining the status of a system, a process or an activity.

30.2.7 N

Nonconformity Non-fulfillment of a requirement.

30.2.8 O

Organization Person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives.

Organizational Knowledge Knowledge specific to the organization, generally gained by experience.

Outsourced Process Process that an external organization performs that is part of the organization's QMS.

30.2.9 P

PDCA Cycle Plan-Do-Check-Act cycle; iterative process for achieving continual improvement.

Performance Measurable result.

Process Set of interrelated or interacting activities that use inputs to deliver an intended result.

Process Environment Set of conditions under which a process is performed.

Product Output of an organization that can be produced without any transaction taking place between the organization and the customer.

30.2.10 Q

Quality Degree to which a set of inherent characteristics of an object fulfills requirements.

Quality Management System (QMS) Part of a management system with regard to quality.

Quality Policy Policy with regard to quality.

Quality Objective Objective with regard to quality.

30.2.11 R

Requirement Need or expectation that is stated, generally implied or obligatory.

Risk Effect of uncertainty on an expected result.

30.2.12 S

Service Output of an organization with at least one activity necessarily performed between the organization and the customer.

Specification Document stating requirements.

Suitability Degree to which established characteristics fulfill requirements.

30.2.13 T

Top Management Person or group of people who directs and controls an organization at the highest level.

Traceability Ability to trace the history, application or location of an object.

30.2.14 V

Validation Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

Verification Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

30.3 Abbreviations

30.3.1 General Abbreviations

BOM - Bill of Materials

CAR - Corrective Action Request

CAPA - Corrective and Preventive Action

DIN - German Institute for Standardization (Deutsches Institut für Normung)

DMAIC - Define, Measure, Analyze, Improve, Control

ERP - Enterprise Resource Planning

FMEA - Failure Mode and Effects Analysis

ISO - International Organization for Standardization

IT - Information Technology

KPI - Key Performance Indicator

NC - Non-Conformity

OEM - Original Equipment Manufacturer

PDCA - Plan-Do-Check-Act

QM - Quality Management

QMS - Quality Management System

QA - Quality Assurance

RACI - Responsible, Accountable, Consulted, Informed

RMA - Return Material Authorization

SLA - Service Level Agreement

SOP - Standard Operating Procedure

SPC - Statistical Process Control

TOC - Table of Contents

WIP - Work in Progress

30.3.2 ISO 9001 Specific Abbreviations

AC - Acceptance Criteria

AR - Audit Report

CA - Corrective Action

CI - Continual Improvement

DI - Documented Information

IP - Interested Party

MR - Management Review

PA - Preventive Action

QO - Quality Objective

QP - Quality Policy

RA - Risk Assessment

SAR - Supplier Audit Report

SOA - Statement of Applicability

30.3.3 Organization-Specific Abbreviations

[**TODO: Add organization-specific abbreviations**]

Examples: - **ABC** - [TODO: Definition] - **XYZ** - [TODO: Definition]

30.4 References

30.4.1 Normative References

ISO 9000:2015 Quality management systems - Fundamentals and vocabulary

ISO 9001:2015 Quality management systems - Requirements

30.4.2 Informative References

ISO 9004 Quality management - Quality of an organization - Guidance to achieve sustained success

ISO 19011 Guidelines for auditing management systems

ISO 31000 Risk management - Guidelines

Note: Terms and definitions from ISO 9000:2015 are authoritative. This appendix serves as a reference for frequently used terms in the QMS.

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