



*QUALITY MANAGEMENT SYSTEM
SERIES ISO 9000:2000
AMERICAN NATIONAL STANDARDS*



QUALITY MANAGEMENT SYSTEM FUNCTIONAL OVERVIEW

**VISION
QUEST**
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A NEW APPROACH TO ISO

Since 1998 there have been several committees grouped under TC 176, which has responded to a survey of 1,100 companies regarding changes to the ISO 9000:1994 Standards and have set forth the current revision now known collectively as ISO 9000:2000 finalized and approved December 13, 2000.

The basic changes to the Quality System Standards are designed to provide the following:

- Base the system architecture on business processes
- Allow for selective application of the requirements as appropriate to the business
- Address continual improvement
- Provide focus on effectiveness of outputs for customers
- Provide focus for efficiency of outputs for management and stakeholders
- Strengthen self-evaluation

The new standards are presented in three series:

ISO 9000:2000, *Quality Management Systems*

Fundamentals and vocabulary

Establishes a starting point for understanding the standards and defines the fundamental terms and definitions used in the ISO 9000 family which you need to avoid misunderstandings in their use.

ISO 9001:2000, *Quality Management Systems*

Requirements

This is the requirement standard you use to assess your ability to meet customer and applicable regulatory requirements and thereby address customer satisfaction.

It is now the only standard in the ISO 9000 family against which third-party certification can be carried.

ISO 9004:2000, *Quality Management Systems*

Guidelines for performance improvements

This guideline standard provides guidance for continual improvement of your quality management system to benefit all parties through sustained customer satisfaction.

The new series are based on 8 specific principles:

1. Customer Satisfaction
2. The role of leadership
3. The involvement of people
4. The business process approach
5. A systematic approach to management
6. Continual improvement
7. A factual approach to decision making
8. Mutually beneficial supplier relationships

These principle manifest themselves into four main clauses

1. Management Responsibility
2. Resource Management
3. Process Management
4. Measurement, Analysis, and Improvement

EIGHT QUALITY MANAGEMENT PRINCIPLES

The eight QMS principles are to be used by senior management as a framework to guide their organizations towards improved performance and attaining ISO 9000:2000 Accreditation. The principles are derived from the collective experience and knowledge of the international experts who participate on the ISO Technical Committee.

The eight quality management principles are defined in ISO 9000:2000, Quality Management Systems Fundamentals and Vocabulary, and in ISO 9004:2000, Quality Management Systems Guidelines for Performance Improvements. The principles are:

- Principle 1 Customer focus
- Principle 2 Leadership
- Principle 3 Involvement of people
- Principle 4 Process approach
- Principle 5 System approach to management
- Principle 6 Continual improvement
- Principle 7 Factual approach to decision making
- Principle 8 Mutually beneficial supplier relationships

The following pages outline the standardized descriptions of the principles as they appear in ISO 9000:2000 and ISO 9004:2000. Examples are provided demonstrating the benefits derived from use of the principle and of actions that managers typically take in applying the principles to improve their organizations' performance.

PRINCIPLE 1 CUSTOMER FOCUS

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

Key benefits:

- Increased revenue and market share obtained through flexible and fast responses to market opportunities.
- Increased effectiveness in the use of the organization's resources to enhance customer satisfaction.
- Improved customer loyalty leading to repeat business.

Applying the principle of customer focus typically leads to:

- Researching and understanding customer needs and expectations.
- Ensuring that the objectives of the organization are linked to customer needs and expectations.
- Communicating customer needs and expectations throughout the organization.
- Measuring customer satisfaction and acting on the results.
- Systematically managing customer relationships.
- Ensuring a balanced approach between satisfying customers and other interested parties (such as owners, employees, suppliers, financiers, local communities and society as a whole).

PRINCIPLE 2 LEADERSHIP

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

Key benefits:

- People will understand and be motivated towards the organization's goals and objectives.
- Activities are evaluated, aligned and implemented in a unified way.
- Miscommunication between levels of an organization will be minimized.

Applying the principle of leadership typically leads to:

- Considering the needs of all interested parties including customers, owners, employees, suppliers, financiers, local communities and society as a whole.
- Establishing a clear vision of the organization's future.

- Setting challenging goals and targets.
- Creating and sustaining shared values, fairness and ethical role models at all levels of the organization.
- Establishing trust and eliminating fear.
- Providing people with the required resources, training and freedom to act with responsibility and accountability.
- Inspiring, encouraging and recognizing people's contributions.

PRINCIPLE 3 INVOLVEMENT OF PEOPLE

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

Key benefits:

- Motivated, committed and involved people within the organization.
- Innovation and creativity in furthering the organization's objectives.
- People being accountable for their own performance.
- People eager to participate in and contribute to continual improvement.

Applying the principle of involvement of people typically leads to:

- People understanding the importance of their contribution and role in the organization.
- People identifying constraints to their performance.
- People accepting ownership of problems and their responsibility for solving them.
- People evaluating their performance against their personal goals and objectives.
- People actively seeking opportunities to enhance their competence, knowledge and experience.
- People freely sharing knowledge and experience.
- People openly discussing problems and issues.

PRINCIPLE 4 PROCESS APPROACH

A desired result is achieved more efficiently when activities and related resources are managed as a process.

Key benefits:

- Lower costs and shorter cycle times through effective use of resources.
- Improved, consistent and predictable results.
- Focused and prioritized improvement opportunities.
- Applying the principle of process approach typically leads to:

- Systematically defining the activities necessary to obtain a desired result.
- Establishing clear responsibility and accountability for managing key activities.
- Analyzing and measuring of the capability of key activities.
- Identifying the interfaces of key activities within and between the functions of the organization.
- Focusing on the factors such as resources, methods, and materials that will improve key activities of the organization.
- Evaluating risks, consequences and impacts of activities on customers, suppliers and other interested parties.

PRINCIPLE 5 SYSTEM APPROACH TO MANAGEMENT

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

Key benefits:

- Integration and alignment of the processes that will best achieve the desired results.
- Ability to focus effort on the key processes.
- Providing confidence to interested parties as to the consistency, effectiveness and efficiency of the organization.

Applying the principle of system approach to management typically leads to:

- Structuring a system to achieve the organization's objectives in the most effective and efficient way.
- Understanding the interdependencies between the processes of the system.
- Structured approaches that harmonize and integrate processes.
- Providing a better understanding of the roles and responsibilities necessary for achieving common objectives and thereby reducing cross-functional barriers.
- Understanding organizational capabilities and establishing resource constraints prior to action.
- Targeting and defining how specific activities within a system should operate.
- Continually improving the system through measurement and evaluation.

PRINCIPLE 6 CONTINUAL IMPROVEMENT

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

Key benefits:

- Performance advantage through improved organizational capabilities.
- Alignment of improvement activities at all levels to an organization's strategic intent.
- Flexibility to react quickly to opportunities.

Applying the principle of continual improvement typically leads to:

- Employing a consistent organization-wide approach to continual improvement of the organization's performance.
- Providing people with training in the methods and tools of continual improvement.
- Making continual improvement of products, processes and systems an objective for every individual in the organization.
- Establishing goals to guide, and measures to track, continual improvement.
- Recognizing and acknowledging improvements.

PRINCIPLE 7 FACTUAL APPROACH TO DECISION MAKING

Effective decisions are based on the analysis of data and information

Key benefits:

- Informed decisions.
- An increased ability to demonstrate the effectiveness of past decisions through reference to factual records.
- Increased ability to review, challenge and change opinions and decisions.

Applying the principle of factual approach to decision making typically leads to:

- Ensuring that data and information are sufficiently accurate and reliable.
- Making data accessible to those who need it.
- Analyzing data and information using valid methods.
- Making decisions and taking action based on factual analysis, balanced with experience and intuition.

PRINCIPLE 8 MUTUALLY BENEFICIAL SUPPLIER RELATIONSHIPS

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value

Key benefits:

- Increased ability to create value for both parties.
- Flexibility and speed of joint responses to changing market or customer needs and expectations.
- Optimization of costs and resources.

Applying the principles of mutually beneficial supplier relationships typically leads to:

- Establishing relationships that balance short-term gains with long-term considerations.
- Pooling of expertise and resources with partners.
- Identifying and selecting key suppliers.
- Clear and open communication.
- Sharing information and future plans.
- Establishing joint development and improvement activities.
- Inspiring, encouraging and recognizing improvements and achievements by suppliers.

FOUR MAIN CLAUSES TO ISO 9000:2000

The four main clauses of the ISO 9000-2000 Standards are:

Clause I – Management Responsibility

- General
- Interested party needs and requirements
- Quality Policy
- Quality objectives and planning
- Quality Management System

Functional Requirements

- Commitment and Involvement
- Quality Policy
- Management system including Documentation Control and Quality Records System
- Stakeholder Needs and Requirements
- Objectives and Planning
- Organizational Structure including Management Structure and Responsibility
- Management System Review

Clause II – Resource Management

- General
- Human Resources
- Other Resources

Functional Requirements

- Material and Utilities including Purchase Control
- Plant and Equipment
- Access to Information and Data Know How Expertise
- Human Resources including Education and Training
- Financial Resource Management

Clause III – Process Management

- General
- Interested Party Related Processes
- Design and Development

- Purchasing
- Production and Service Operations

Functional Requirements

- Review of Agreements
- Design and Development Control including Identification and Traceability
- Handling, Storage, and Preservation
- Process Control including Measurement and Test Equipment Control and Inspection and Test Status
- Control of Non-Conforming Product
- Deliver of Service Control

Clause IV – Measurement, Analysis, and Improvement

- General
- Measurement
- Analysis of Data

Functional Requirements

- Internal Audit
- Product Related Measurement
- Improvement Process
- Process Related Measurements
- Analysis of Data
- Corrective Action
- Preventative Action

The ISO 9000:2000 Standards promote the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

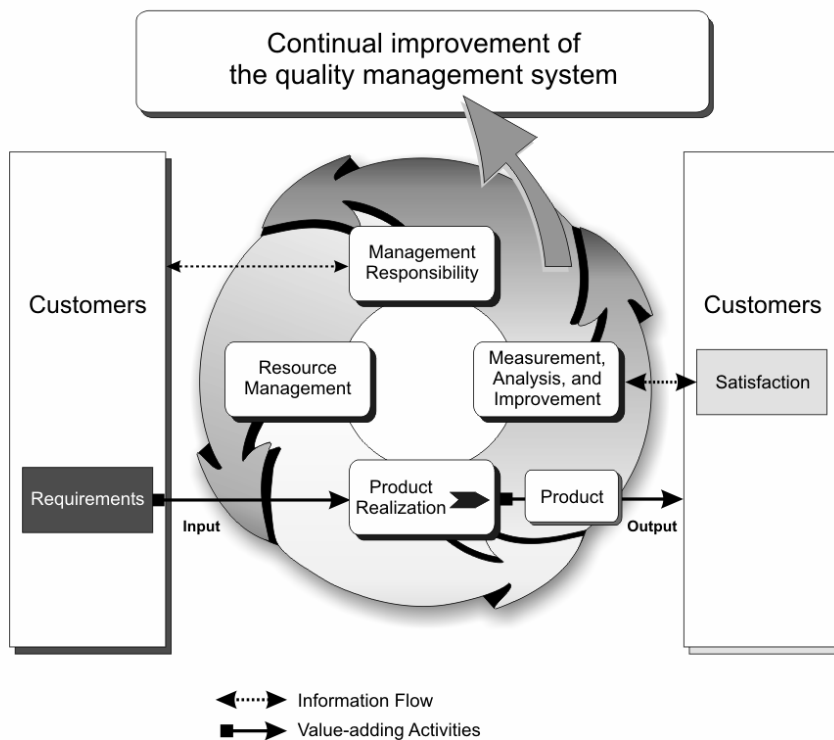
- Understanding and meeting requirements
- The need to consider processes in terms of added value
- Obtaining results of process performance and effectiveness
- Continual improvement of processes based on objective measurement

What does this translate to in terms of organizational structure?

ISO 9000:1994 focused on the organization as if each functional entity (i.e. Sales, Customer Service, and Operations) was a self-contained entity.

ISO 9000:2000 focuses on the organization as if all functional entities must work together cross-functionally.

PROCESS-BASED QUALITY MANAGEMENT SYSTEM MODEL



Differences between the 1994 and 2000 Standards

Items in blue are new requirements; items in red are items that will be concentrated on by auditors.

ISO 9001:1994 (Current Quality System)

- 4.1 Management Responsibility
- 4.2 Quality System
- 4.3 Contract Review
- 4.5 Document and Data Control
- 4.6 Purchasing
- 4.7 Control of Customer Supplied Product
- 4.8 Product Identification and Trace ability
- 4.9 Process Control
- 4.10 Inspection and Testing
- 4.11 Control of Inspection, Measuring, and Test Equipment
- 4.12 Inspection and Test Status
- 4.13 Control of Non-Conforming Product
- 4.14 Corrective and Preventative Action
- 4.15 Handling, Storage, Packaging, Preservation, and Delivery
- 4.16 Control of Quality Records
- 4.17 Internal Quality Audits
- 4.18 Training
- 4.19 Servicing
- 4.20 Statistical Techniques

ISO 9001:2000

Clause I – Management Responsibility

- 4.1 Management Responsibility
- 4.2 Quality System
- 4.3 Contract Review
- Planning
- Outline of Stakeholder Needs
- Quality Management System Review

Clause II – Resource Management

- 4.6 Purchasing
- 4.18 Training
- Material and Utilities including Purchase Control
- Plant and Equipment
- Access to Information and Data Know How Expertise
- Financial Resource Management

Clause III – Process Management

- 4.3 Contract Review
- 4.7 Control of Customer Supplied Product
- 4.8 Product Identification and Trace ability
- 4.9 Process Control
- 4.10 Inspection and Testing
- 4.11 Control of Inspection, Measuring, and Test Equipment
- 4.12 Inspection and Test Status
- 4.13 Control of Non-Conforming Product
- 4.15 Handling, Storage, Packaging, Preservation, and Delivery
- 4.16 Control of Quality Records

Clause IV – Measurement, Analysis, and Improvement

- 4.5 Document and Data Control
- 4.14 Corrective and Preventative Action
- 4.17 Internal Quality Audits
- 4.19 Servicing
- 4.20 Statistical Techniques
- Product Related Measurement
- Improvement Process
- Process Related Measurements
- Analysis of Data

CORRESPONDENCE BETWEEN STANDARDS ISO 9001:1994 AND ISO 9001:2000

| ISO 9001:1994 | ISO 9001:2000 |
|--------------------------------------|---|
| 1 Scope | 1 Scope |
| 2 Normative Reference | 2 Normative Reference |
| 3 Definitions | 3 Terms and Definitions |
| 4 Quality System Requirements | |
| 4.1 Management responsibility | |
| 4.1.1 Quality policy | 5.1 Management commitment 5.3 Quality policy 5.4.1 Quality objectives |
| 4.1.2 Organization | |
| 4.1.2.1 Responsibility and authority | 5.5.1 Responsibility and authority |
| 4.1.2.2 Resources | 6.1 Provision of resources 6.2.1 General |
| 4.1.2.3 Management representative | 5.5.2 Management representative |
| 4.1.3 Management review | 5.6:1 General 8.5.1 Continual improvement |
| 4.2 Quality system | |
| 4.2.1 General | 4.1 General requirements 4.2.2 Quality manual |
| 4.2.2 Quality system procedures | 4.2.1 General |
| 4.2.3 Quality planning | 5.4.2 Quality management system planning 7.1 Planning of product realization |
| 4.3 Contract review | |
| 4.3.1 General | |
| 4.3.2 Review | 5.2 Customer focus 7.2.1 Determination of requirements related to the product 7.2.2 Review of requirements related to the product 7.2.3 Customer communication |
| 4.3.3 Amendment to a contract | 7.2.2 Review of requirements related to the product |
| 4.3.4 Records | 7.2.2 Review of requirements related to the product |

4.4 Design control

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| 4.4.1 General | |
| 4.4.2 Design and development planning | 7.3.1 Design and development planning |
| 4.4.3 Organizational and technical interlaces | 7.3.1 Design and development planning |
| 4.4.4 Design input | 7.2.1 Determination of requirements related to the product 7.3.2 Design and development inputs |
| 4.4.5 Design output | 7.3.3 Design and development outputs |
| 4.4.6 Design review | 7.3.4 Design and development review |
| 4.4.7 Design verification | 7.3.5 Design and development verification |
| 4.4.8 Design validation | 7.3.6 Design and development validation |
| 4.4.9 Design changes | 7.3.7 Control of design and development changes |

4.5 Document and data control

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| 4.5.1 General | 4.2.3 Control of documents |
| 4.5.2 Document and data approval and issue | 4.2.3 Control of documents |
| 4.5.3 Document and data changes | 4.2.3 Control of documents |

4.6 Purchasing

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| 4.6.1 General | |
| 4.6.2 Evaluation of subcontractors | 7.4.1 Purchasing process |
| 4.6.3 Purchasing data | 7.4.2 Purchasing information |
| 4.6.4 Verification of purchased product | 7.4.3 Verification of purchased product |

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| 4.7 Control of customer-supplied product | 7.5.4 Customer property |
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| 4.8 Product identification and traceability | 7.5.3 Identification and traceability |
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| 4.9 Process control | 6.3 Infrastructure 6.4 Work environment 7.5.1 Control of production and service provision 7.5.2 Validation of processes for production and service provision |
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4.10 Inspection and testing

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| 4.10.1 General | 7.1 Planning of product realization 8.1 General |
| 4.10.2 Receiving inspection and testing | 7.4.3 Verification of purchased product 8.2.4 Monitoring and measurement of product |
| 4.10.3 In-process inspection and testing | 8.2.4 Monitoring and measurement of product |
| 4.10.4 Final inspection and testing | 8.2.4 Monitoring and measurement of product |
| 4.10.5 Inspection and test records | 7.5.3 Identification and traceability 8.2.4 Monitoring and measurement of product |

4.11 Control of inspection, measuring and test equipment

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| 4.11.1 General | 7.6 Control of monitoring and measuring devices |
| 4.11.2 Control procedure | 7.6 Control of monitoring and measuring devices |

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| 4.12 Inspection and test status | 7.5.3 Identification and traceability |
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4.13 Control of nonconforming product

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| 4.13.1 General | 8.3 Control of nonconforming product |
| 4.13.2 Review and disposition of nonconforming product | 8.3 Control of nonconforming product |

4.14 Corrective and preventive action

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| 4.14.1 General | 8.5.2 Corrective action 8.5.3 Preventive action |
| 4.14.2 Corrective action | 8.5.2 Corrective action |
| 4.14.3 Preventive action | 8.5.3 Preventive action |

4.15 Handling, storage, packaging, preservation & delivery

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| 4.15.1 General | |
| 4.15.2 Handling | 7.5.5 Preservation of product |
| 4.15.3 Storage | 7.5.5 Preservation of product |
| 4.15.4 Packaging | 7.5.5 Preservation of product |
| 4.15.5 Preservation | 7.5.5 Preservation of product |
| 4.15.6 Delivery | 7.5.1 Control of production and service provision |

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| 4.16 Control of quality records | 4.2.4 Control of records |
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| 4.17 Internal quality audits | 8.2.2 Internal audit 8.2.3 Monitoring and measurement of processes |
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| 4.18 Training | 6.2.2 Competence, awareness and training |
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| 4.19 Servicing | 7.5.1 Control of production and service provision |
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4.20 Statistical techniques

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| 4.20.1 Identification of need | 8.1 General 8.2.3 Monitoring and measurement of processes 8.2.4 Monitoring and measurement of product 8.4 Analysis of data |
| 4.20.2 Procedures | 8.1 General 8.2.3 Monitoring and measurement of processes 8.2.4 Monitoring and measurement of product 8.4 Analysis of data |

CORRESPONDENCE BETWEEN STANDARDS ISO 9001:2000 AND ISO 9001:1994

ISO 9001:2000

ISO 9001:1994

| | |
|-----------------|---------|
| 1 Scope | 1 Scope |
| 1.1 General | |
| 1.2 Application | |

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| 2 Normative Reference | 2 Normative Reference |
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| 3 Terms and Definitions | 3 Definitions |
|-------------------------|---------------|

4 Quality management system

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| 4.1 General requirements | |
| 4.2 Documentation requirements | |
| 4.2.1 General | 4.2.2 Quality system procedures |
| 4.2.2 Quality manual | 4.2.1 General |
| 4.2.3 Control of documents | 4.5.1 General 4.5.2 Document and data approval and issue 4.5.3 Document and data changes |
| 4.2.4 Control of records | 4.16 Control of quality records |

5 Management responsibility

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| 5.1 Management commitment | 4.1.1 Quality policy |
| 5.2 Customer focus | 4.3.2 Review |
| 5.3 Quality policy | 4.1.1 Quality policy |
| 5.4 Planning [only] | |
| 5.4.1 Quality objectives | 4.1.1 Quality policy |
| 5.4.2 Quality management system planning | 4.2.3 Quality planning |
| 5.5 Responsibility, authority and communication | |
| 5.5.1 Responsibility and authority | 4.1.2.1 Responsibility and authority |
| 5.5.2 Management representative | 4.1.2.3 Management representative |
| 5.5.3 Internal communication | |
| 5.6 Management review | |
| 5.6:1 General | 4.1.3 Management review |
| 5.6.2 Review input | |
| 5.6.3 Review output | |

6 Resource management

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| 6.1 Provision of resources | 4.1.2.2 Resources |
| 6.2 Human resources | |
| 6.2.1 General | 4.1.2.2 Resources |
| 6.2.2 Competence, awareness and training | 4.18 Training |
| 6.3 Infrastructure | 4.9 Process control |
| 6.4 Work environment | 4.9 Process control |

7 Product realization

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| 7.1 Planning of product realization | 4.2.3 Quality planning 4.10.1 General |
| 7.2 Customer-related processes | |
| 7.2.1 Determination of requirements related to the product | 4.3.2 Review 4.4.4 Design input |
| 7.2.2 Review of requirements related to the product | 4.3.2 Review 4.3.3 Amendment to a contract 4.3.4 Records |
| 7.2.3 Customer communication | 4.3.2 Review |
| 7.3 Design and development | |
| 7.3.1 Design and development planning | 4.4.2 Design and development planning 4.4.3 Organizational and technical interlaces |
| 7.3.2 Design and development inputs | 4.4.4 Design input |
| 7.3.3 Design and development outputs | 4.4.5 Design output |
| 7.3.4 Design and development review | 4.4.6 Design review |
| 7.3.5 Design and development verification | 4.4.7 Design verification |
| 7.3.6 Design and development validation | 4.4.8 Design validation |
| 7.3.7 Control of design and development changes | 4.4.9 Design changes |
| 7.4 Purchasing | |
| 7.4.1 Purchasing process | 4.6.2 Evaluation of subcontractors |
| 7.4.2 Purchasing information | 4.6.3 Purchasing data |
| 7.4.3 Verification of purchased product | 4.6.4 Verification of purchased product 4.10.2 Receiving inspection and testing |
| 7.5 Production and service provision | |
| 7.5.1 Control of production and service provision | 4.9 Process control 4.15.6 Delivery 4.19 Servicing |
| 7.5.2 Validation of processes for production and service provision | 4.9 Process control |
| 7.5.3 Identification and traceability | 4.8 Product identification and traceability 4.10.5 Inspection and test records 4.12 Inspection and test status |
| 7.5.4 Customer property | 4.7 Control of customer-supplied product |
| 7.5.5 Preservation of product | 4.15.2 Handling 4.15.3 Storage 4.15.4 Packaging 4.15.5 Preservation |
| 7.6 Control of monitoring and measuring devices | 4.11.1 General 4.11.2 Control procedure |

8 Measurement, analysis and improvement

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| 8.1 General | 4.10.1 General 4.20.1 Identification of need 4.20.2 Procedures |
| 8.2 Monitoring and measurement | |
| 8.2.1 Customer satisfaction | |
| 8.2.2 Internal audit | 4.17 Internal quality audits |
| 8.2.3 Monitoring and measurement of processes | 4.17 Internal quality audits 4.20.1 Identification of need 4.20.2 Procedures |
| 8.2.4 Monitoring and measurement of product | 4.10.2 Receiving inspection and testing 4.10.3 In-process inspection and testing 4.10.4 Final inspection and testing 4.10.5 Inspection and test records 4.20.1 Identification of need 4.20.2 Procedures |
| 8.3 Control of nonconforming product | 4.13.1 General 4.13.2 Review and disposition of nonconforming product |
| 8.4 Analysis of data | 4.20.1 Identification of need 4.20.2 Procedures |
| 8.5 Improvement | |
| 8.5.1 Continual improvement | 4.1.3 Management review |
| 8.5.2 Corrective action | 4.14.1 General 4.14.2 Corrective action |
| 8.5.3 Preventive action | 4.14.1 General 4.14.3 Preventive action |