ISO 9000
Quality Management System

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Definitions

- The laboratory product
- The laboratory process
- The laboratory customer
- The satisfaction
- The improvement

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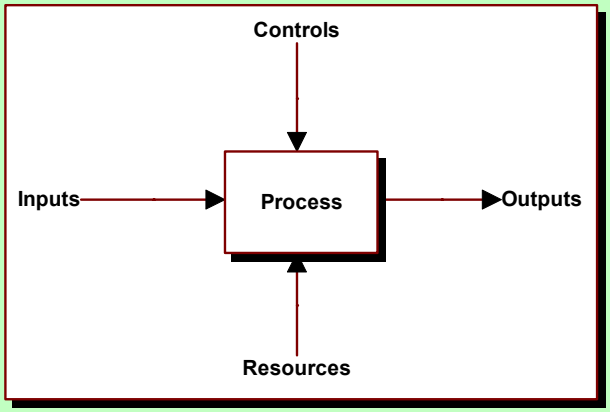
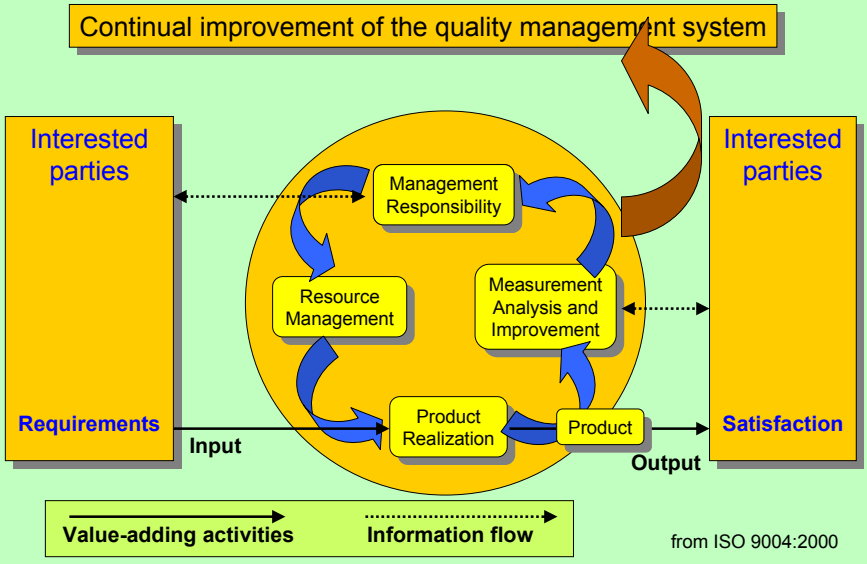
The Process Approach



Model of a Process-based Quality Management System



from ISO 9004:2000

4 Quality Management System

- 4.1 General requirements
- 4.2 Documentation requirements
  - 4.2.1 General
  - 4.2.2 Quality manual
  - 4.2.3 Control of documents
  - 4.2.4 Control of records

4 QUALITY MANAGEMENT SYSTEM
4.1 General Requirements

- Quality management system (QMS)
- Continual improvement
- Sequence and interaction of processes
- Effective operation and control of processes
- Availability of resources and information
- Monitor, measure and analyze processes
- Achieve planned results
- Improve processes
- Outsourcing of processes

4 QUALITY MANAGEMENT SYSTEM
4.2 Documentation Requirements

4.2.1 General

- Quality policy
- Quality objectives
- Quality manual
- Procedures
- Work instructions
- Records

4 QUALITY MANAGEMENT SYSTEM
4.2 Documentation Requirements

4.2.2 Quality manual

- The laboratory quality manual shall include:
  - The scope of the quality management system
  - Links to the laboratory procedures
  - Interactions between the processes of the QMS

4 QUALITY MANAGEMENT SYSTEM
4.2 Documentation Requirements

4.2.3 Control of documents

- Approval of documents
- Review, update and re-approval of documents
- Identification of changes and current revisions
- Availability of documents at points of use
- Documents to be legible and readily identifiable
- Control of external documents
- Control of obsolete documents
- Archives

4 QUALITY MANAGEMENT SYSTEM
4.2 Documentation Requirements

4.2.4 Control of records

- Objective evidence of conformity to requirements
- Legible, readily identifiable, retrievable
- Documented procedure for the identification, storage, protection, retrieval, retention time and disposition of records

5 Management Responsibility

- 5.1 Management commitment
- 5.2 Customer focus
- 5.3 Quality policy
- 5.4 Planning
  - 5.4.1 Quality objectives
  - 5.4.2 Quality management system planning
- 5.5 Responsibility, authority and communication
  - 5.5.1 Responsibility and authority
  - 5.5.2 Management representative
  - 5.5.3 Internal communication
- 5.6 Management review
  - 5.6.1 General
  - 5.6.2 Review input
  - 5.6.3 Review output

5 MANAGEMENT RESPONSIBILITY
5.1 Management Commitment

- Addressing customer requirements
- Establishing the quality policy
- Ensuring that quality objectives are established
- Conducting management reviews
- Ensuring the availability of resources

5 MANAGEMENT RESPONSIBILITY
5.2 Customer Focus

- Satisfaction of the needs and expectation of the current and future customers
- Internal and external customers
- The interested parties

5 MANAGEMENT RESPONSIBILITY
5.3 Quality Policy

- Appropriate to the purpose of the laboratory
- Commitment to compliance with requirements
- How quality objectives are established and reviewed
- Communicated and understood within the laboratory
- Reviewed for continuing suitability

5 MANAGEMENT RESPONSIBILITY
5.4 Planning

5.4.1 Quality objectives

- The quality objectives of the various functions and levels within the laboratory shall be established and be consistent with the quality policy and the laboratory strategy

5 MANAGEMENT RESPONSIBILITY
5.4 Planning

5.4.2 Quality management system planning

- Meet the general requirements for the quality management system (4.1)
- Management of change

5 MANAGEMENT RESPONSIBILITY
5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and authority

- Responsibilities and authorities of laboratory personnel should be defined and communicated within the laboratory

5 MANAGEMENT RESPONSIBILITY
5.5 Responsibility, Authority and Communication

5.5.2 Management representative

- Member of the organization
- Ensures the proper operation of the quality management system
- Reports to the top management
- Promotes the awareness of customer requirements throughout the organization

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5 MANAGEMENT RESPONSIBILITY
5.5 Responsibility, Authority and Communication

5.5.3 Internal communication

- Communication channels within the laboratory
- Communication as the stimulus for an effective QMS

5 MANAGEMENT RESPONSIBILITY
5.6 Management Review

5.6.1 General

- Review of the system at planned intervals
- Assessment of opportunities for improvement
- Needs for changes
- Records of management reviews

5 MANAGEMENT RESPONSIBILITY
5.6 Management Review

5.6.2 Review input

- Results of audit and self-assessment
- Feedback from customer and from benchmarking activities
- Performance of the laboratory activity
- Any recommendations for improvement (corrective and preventive actions, suggestions from laboratory personnel)

5 MANAGEMENT RESPONSIBILITY
5.6 Management Review

5.6.3 Review output

- Decisions and actions resulted from the management review meetings that will improve the effectiveness of the system and the quality of the laboratory product

6 Resource Management

- 6.1 Provision of resources
- 6.2 Human resources
  - 6.2.1 General
  - 6.2.2 Competence, awareness and training
- 6.3 Infrastructure
- 6.4 Work environment

6 RESOURCE MANAGEMENT
6.1 Provision of Resources

- Provision of the resources needed for:
  - The implementation and maintenance of the QMS
  - Realization of customer satisfaction

6 RESOURCE MANAGEMENT
6.2 Human Resources

6.2.1 General

- Appropriate education, training, skills and experience of the laboratory personnel

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6 RESOURCE MANAGEMENT
6.2 Human Resources

6.2.2 Competence, awareness and training

- Determination of necessary competence of the laboratory personnel
- Provision of training
- Evaluation of the effectiveness of the action taken
- Awareness of personnel of the relevance and importance of their activities
- Maintenance of training records

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6 RESOURCE MANAGEMENT
6.3 Infrastructure

- Building and workspace
- Process equipment
- Supporting services (transportation, communication)
- Information systems

6 RESOURCE MANAGEMENT
6.4 Work Environment

- The work environment in the laboratory shall be determined and managed in a way to encourage people in achieving conformity to product requirements

7 Product Realization

- 7.1 Planning of product realization
- 7.2 Customer-related processes
  - 7.2.1 Determination of requirements related to product
  - 7.2.2 Review of requirements related to product
  - 7.2.3 Customer communication
- 7.3 Design and development
  - 7.3.1 Design and development planning
  - 7.3.2 Design and development inputs
  - 7.3.3 Design and development output
  - 7.3.4 Design and development review
  - 7.3.5 Design and development verification
  - 7.3.6 Design and development validation
  - 7.3.7 Control of design and development changes

7 Product Realization

- 7.4 Purchasing
  - 7.4.1 Purchasing processes
  - 7.4.2 Purchasing information
  - 7.4.3 Verification of purchased products
- 7.5 Product and service provision
  - 7.5.1 Control of production and service provisions
  - 7.5.2 Validation of processes for production and service provisions
  - 7.5.3 Identification and traceability
  - 7.5.4 Customer property
  - 7.5.5 Preservation of product
- 7.6 Control of monitoring and measuring devices

7 PRODUCT REALIZATION
7.1 Planning of Product Realization

- Quality objectives and product specification
- Establishment of processes and documents and provision of resources specific to the product
- Verification, validation, monitoring, inspection, and test activities specific to the product and
- Criteria for product acceptance
- Records

7 PRODUCT REALIZATION
7.2 Customer Related Processes

7.2.1 Determination of requirements related to the product

- Requirements specified by the customer
- Requirements necessary for specified or intended use
- Statutory and regulatory requirements
- Requirements determined by the organization

7 PRODUCT REALIZATION
7.2 Customer Related Processes

7.2.2 Review of requirements related to the product

- Definition of product requirements
- Resolution of contract or order requirements
- Ability to meet the defined requirements
- Records of the results of the review and action
- Confirmation of customer requirements and re-confirmation in case of changes
- Awareness of relevant personnel

7 PRODUCT REALIZATION
7.2 Customer Related Processes

7.2.3 Customer communication

- The laboratory shall communicate with its customers to get information on the laboratory products and feedback from customers including customer complaints

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7 PRODUCT REALIZATION
7.3 Design and Development

7.3.1 Design and development (D&D) planning

- Design and development stages
- Review, verification and validation
- Responsibilities and authorities
- Effective communication between D&D groups
- Update of planning output

7 PRODUCT REALIZATION
7.3 Design and Development

7.3.2 Design and development inputs

- Functional and performance requirements
- Statutory and regulatory requirements
- Information from similar design
- Other relevant information

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7 PRODUCT REALIZATION
7.3 Design and Development

7.3.3 Design and development output

- Meeting the input requirements
- Providing information for purchasing, production and servicing
- Defining acceptance criteria
- Providing parameters for the safe and proper use of the product

7 PRODUCT REALIZATION
7.3 Design and Development

7.3.4 Design and development review

- Systematic reviews at suitable stages
- Evaluation of D&D results
- Identification of problems
- Proposal of necessary action

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7 PRODUCT REALIZATION
7.3 Design and Development

- 7.3.5 Design and development verification
- 7.3.6 Design and development validation
- 7.3.7 Control of design and development changes

7 PRODUCT REALIZATION
7.4 Purchasing

7.4.1 Purchasing process

- Definition of purchase requirements
- Conformance of purchased product to purchase requirements
- Control to the supplier and the purchased product
- Criteria for selection, evaluation and re-evaluation of suppliers
- Evaluation results to be recorded

7 PRODUCT REALIZATION
7.4 Purchasing

7.4.2 Purchasing information

- Definition of the characteristics of the product to be purchased
- What is required for the approval of the purchased product, procedures, processes and equipment?
- What are the necessary qualifications of personnel?
- What are the QMS requirements?

7 PRODUCT REALIZATION
7.4 Purchasing

7.4.3 Verification of purchased product

- Inspection of purchased material
- Purchased product to meet specified purchase requirements
- Verification at the supplier's premises
  - Define verification arrangements
  - Define method of product release

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7 PRODUCT REALIZATION
7.5 Production and Service Provision

7.5.1 Control of production and service provision

- Production and service provision under controlled conditions such as
  - Availability of information relevant to the characteristics of the products
  - Availability of work instructions
- …

7 PRODUCT REALIZATION
7.5 Production and Service Provision

7.5.1 Control of production and service provision (contd.)

- Availability of suitable equipment
- Availability and use of monitoring and measuring devices
- Monitoring and measurement
- Release, delivery and post-delivery activities

7 PRODUCT REALIZATION
7.5 Production and Service Provision

7.5.2 Validation of processes for production and service provision

- Ability of processes to achieve planned results
- Verification of processes by monitoring or measurement of the resulting output
- Validation of processes for production and service provision
- …

7 PRODUCT REALIZATION
7.5 Production and Service Provision

7.5.2 Validation of processes for production and service provision (contd.)

- Arrangements for processes for production and service provision
  - Criteria for review and approval of the processes
  - Approval of equipment and qualification of personnel
  - Use of specific methods and procedures
  - Requirements for records
  - Re-validation

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7 PRODUCT REALIZATION
7.5 Production and Service Provision

7.5.3 Identification and traceability

- Identification of the laboratory product (i.e. the laboratory results)
- Status of the laboratory product
- Traceability of laboratory results back to the raw data

7 PRODUCT REALIZATION
7.5 Production and Service Provision

7.5.4 Customer property

- Protection of the customer's property that is under the control or is being used by the laboratory
- Customers to be informed if their product is damaged or unsuitable
- Records of any damaged or unsuitable property
- Intellectual property

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7 PRODUCT REALIZATION
7.5 Production and Service Provision

7.5.5 Preservation of product

- Processes for handling, packaging, storage, preservation and delivery of product
- Prevention of damage, deterioration or misuse
- Involvement of suppliers to effective protection of purchased materials

7 PRODUCT REALIZATION
7.6 Control of Measuring and Monitoring Devices

- Determination of the necessary monitoring and measurements
- Processes to ensure that this activity is carried out
- Determination of the necessary monitoring and measurement devices

…

7 PRODUCT REALIZATION
7.6 Control of Measuring and Monitoring Devices

- Calibration or verification of devices
- Adjustment of devices
- Identification of calibration status
- Protection from damage and deterioration
- Assessment of the validity of previous results
- Appropriate action to affected product or equipment
- Calibration records

8 Measurement, Analysis and Improvement

- 8.1 General
- 8.2 Monitoring and measurement
  - 8.2.1 Customer satisfaction
  - 8.2.2 Internal audit
  - 8.2.3 Monitoring and measurement of processes
  - 8.2.4 Monitoring and measurement of product
- 8.3 Control of non-conforming product
- 8.4 Analysis of data
- 8.5 Improvement
  - 8.5.1 Continual improvement
  - 8.5.2 Corrective action
  - 8.5.3 Preventive action

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT
8.1 General

- Implementation of processes for monitoring, measurement, analysis and improvement of the laboratory activity and the continual improvement of the effectiveness of the Quality Management System

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT
8.2 Monitoring and Measurement

8.2.1 Customer satisfaction

- Meeting customer requirements
- Processes to collect, analyze and use of customer-related information
- Customer surveys
- Measurement of customer satisfaction
- Customer complaints

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT
8.2 Monitoring and Measurement

8.2.2 Internal audit

- Internal Audit at planned intervals
- System conformance to planned arrangements and to the QMS
- Effective implementation and maintenance of the system

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT
8.2 Monitoring and Measurement

8.2.2 Internal audit

- Audit program
  - Status and importance of processes
  - Areas to be audited
  - Results of previous audit
- Selection of auditors
  - Objectivity and impartiality
  - Not to audit their own work

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8 MEASUREMENT, ANALYSIS AND IMPROVEMENT
8.2 Monitoring and Measurement

8.2.2 Internal audit

- Internal audit procedure
- Elimination of non conformities and their causes
- Follow up activities

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT
8.2 Monitoring and Measurement

8.2.3 Monitoring and measurement of processes

- Ability of processes to achieve planned results
- Evaluation of process performance

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8 MEASUREMENT, ANALYSIS AND IMPROVEMENT
8.2 Monitoring and Measurement

8.2.4 Monitoring and measurement of product

- Ability of product to satisfy the purpose
- Conformity to the acceptance criteria
- Qualified persons to release products

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT
8.3 Control of non-conforming products

- Identification of non-conforming products
- Procedure for non-conforming products
- Elimination of non-conformity
- Release under concession by a relevant authority or by the customer
- Records for non-conformities and concession
- Re-verification of corrected products
- Completion of planned arrangements before release

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT
8.4 Analysis of Data

- Analysis of data
  - Suitability and effectiveness of the QMS
  - Continual improvement
- Customer satisfaction
- Conformity to product requirements
- Trends of processes
- Opportunities for preventive action
- Performance of suppliers

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8 MEASUREMENT, ANALYSIS AND IMPROVEMENT
8.5 Improvement

8.5.1 Continual improvement

- Improvement of the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review
- Small-step improvements
- Strategic breakthrough improvements
- Process for the identification and management of improvement activities

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8 MEASUREMENT, ANALYSIS AND IMPROVEMENT
8.5 Improvement

8.5.2 Corrective action

- Elimination of causes of non-conformity
- Prevention of recurrence
- Documented procedure
  - Review of non-conformities and customer complaints
  - Causes of non-conformities
  - Need for action
  - Records of the results of action taken
  - Reviewing the effectiveness of the corrective action taken

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT
8.5 Improvement

8.5.3 Preventive action

- Elimination of causes of potential non-conformity
- Prevention of occurrences
- Documented procedure
  - Determination of potential non-conformities and their causes
  - Evaluation of the need for action
  - Implementation of action
  - Records of the results of action taken
  - Reviewing the effectiveness of the preventive action taken

Summary

- ISO 9000 basic requirements
  - Quality management system
  - Management responsibility
  - Resource management
  - Product realization
  - Measurement, analysis and improvement
- The process approach
- Documented quality management system
- Objective evidence of the conformance of the laboratory activities to the requirements

Where to Get More Information

- Quality Management Systems – Requirements
  ISO 9001:2008
- Quality Management Systems - Guidelines for performance improvements
  ISO 9004:2000
- http://www.iso.org