

Quality Management and Leadership

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EAHP Foundation seminar
Vilnius 2009



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No Conflict of Interest

EAHP Foundation seminar
Vilnius 2009

Schedule

09:00 - 09:30	Quality Management Systems
09:30 - 10:00	Training, Competence and Awareness
10:00 - 10:30	Control of Documents and Records
10:30 - 11:00	Coffee Break
11:00 - 11:30	Improvement
11:30 - 12:00	Management Process
12:00 - 12:30	Briefing for workshops
14:00 - 16:00	Workshops
16:00 - 16:15	Coffee Break
16:15 - 17:45	Presentation of workshops, discussion

Schedule

09:00 - 09:30 **Quality Management Systems**

09:30 - 10:00 Training, Competence and Awareness

10:00 - 10:30 Control of Documents and Records

10:30 - 11:00 Coffee Break

11:00 - 11:30 Improvement

11:30 - 12:00 Management Process

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Quality ... Qualities ... (ISO 9000:2005)

Quality - Degree to which a set of inherent characteristics fulfills requirements

Quality control - part of quality management focused on fulfilling quality requirements

Quality assurance - part of quality management focused on providing confidence that quality requirements will be fulfilled

Quality improvement - part of quality management focused on increasing the ability to fulfil quality requirements

Quality management - coordinated activities to direct and control an organization with regard to quality

Leadership (ISO 9000:2005)

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.

Historical

- Guilds in earlier times - quality control (good or not)
- Mass production during industrial revolution - focus upon production against lower cost with increased efficiency
- Car industry - mass production
- Aerospace - mainly preventive measures, risk management
- Nowadays - many different industries and branches use quality management

Quality Management Systems

- EFQM
- JCIA
- KTQ
- ISO 9001
- ...

EFQM

European Foundation for Quality Management

Founded 1989, headquarters in Brussels, Belgium

Framework to support organizations and their senior leaders to implement strategies

9 criteria

5 **enablers** (Leadership, People, Policy & Strategy, Partnerships & Resources, Processes);

4 **results** (People Results, Client Results, Society Results, Key Performance Results))

Assessments by notified bodies.

EFQM (2)

- Diagnostic tool for assessing the health of an organization (self-assessment)
- Assessment - levels of Excellence
 - „Committed to Excellence“
 - „Recognised for Excellence“

JCIA

Joint Commission International Accreditation

Founded 1951, USA

Not a quality management system, but a catalogue of criteria for an entire hospital/clinic.

Accreditation by Joint Commission.

JCIA (2)

Focused on Patients:

- Access to Care and Continuity of Care
- Patient and Family Rights
- Assessment of Patients
- Care of Patients
- Patient and Family Education

Focused on Management:

- Quality Improvement and Patient Safety
- Prevention and Control of Infections
- Governance, Leadership and Direction
- Facility Management and Safety
- Staff Qualifications and Education
- Management of Information

KTQ

Kooperation für Transparenz und Qualität im Gesundheitswesen
(Cooperation for transparency and Quality in Health Care)

Founded 2001

Not a quality management system, but a catalogue of criteria for an entire hospital/clinic.

72 criteria, including 25 core criteria.

Certification by notified bodies („Visits“)

ISO 9001:2008

International Standardization Organization

First standard published in 1987

Although the standard originated in manufacturing, it is now employed in several types of organizations; a „product“ can mean a physical object, a service or softwares.

Model of a process-based quality management system (ISO 9001:2008)

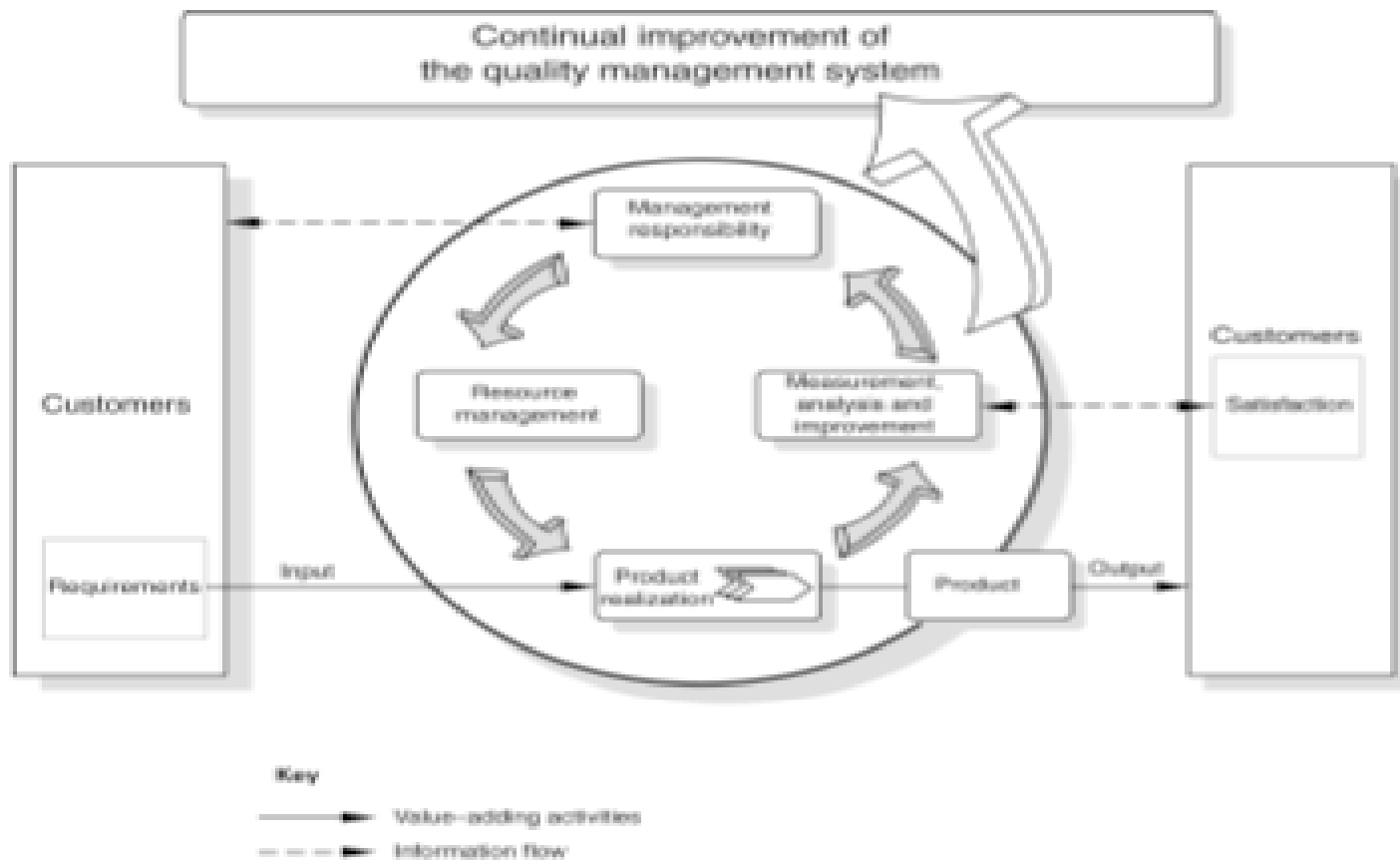


Figure 1 — Model of a process-based quality management system

Contents of ISO 9001:2008

1. Scope

1.1 General

1.2 Application

2. Normative references

3. Terms and definitions

4. Quality management system

4.1 General requirements

4.2 **Documentation requirements** (Control of Documents and Records)

Contents of ISO 9001:2008 (2)

5. Management responsibility (Management process)

5.1 Management commitment

5.2 Customer focus

5.3 Quality policy

5.4 Planning

5.5 Responsibility, authority and communication

5.6 Management review

6. Resource management

6.1 Provision of resources

6.2 **Human resources** (Training, Competence and Awareness)

6.3 Infrastructure

6.4 Work environment

Contents of ISO 9001:2008 (3)

7. Product realization

- 7.1 Planning of product realization
- 7.2 Customer-related process
- 7.3 Design and development
- 7.4 Purchasing
- 7.5 Production and service provision
- 7.6 Control of monitoring and measuring equipment

Contents of ISO 9001:2008 (4)

8. Measurement, analysis and improvement

8.1 General

8.2 Monitoring and measurement

8.3 Control of nonconforming product

8.4 Analysis of data

8.5 **Improvement** (Improvement)

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Training, competence and awareness

6.2.2 Competence, training and awareness

The organization shall

- Determine the necessary **competence** for personnel performing work affecting conformity requirements,
 - ✓ Define roles in your organization and check for education, training and qualification requirements
- Where applicable, provide **training** or take other actions to achieve the necessary competence,
 - ✓ Training for new personnel
 - ✓ Education for existing personnel
- **Evaluate** the effectiveness of the actions taken,
 - ✓ Qualification of personnel; has the training action taken been effective?

Training, competence and awareness (2)

- Ensure that its personnel are **aware** of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
 - ✓ Inform personnel about their contribution to the production or service provision
- Maintain appropriate **records** of education, training, skills and experience
 - ✓ See „Control of documents and records“!

Training, competence and awareness (3)

Aims for the workshop:

- Establish a procedure for personnel training
- Define roles in your organization and establish job descriptions
- Establish a checklist for training of new personnel
- Establish an annual education plan for personnel

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Control of Documents and Records

4.2.3 Control of documents

A documented procedure shall be established to define the controls needed to

- **Approve documents** for adequacy prior to use,
 - ✓ Who shall write a new document?
 - ✓ Who shall check a document prior to release? What is the aim of checking?
 - ✓ Who shall release a document?
- To **review** and update as necessary and re-approve documents,
 - ✓ Who shall change an existing document?
 - ✓ What is the frequency to check existing documents for adequacy?

Control of Documents and Records (2)

- To ensure that changes and the current **revision status** of documents are identified,
 - ✓ Version control; e.g. 1, 2, 3, ... or date of release
- To ensure that relevant versions of applicable documents are **available** at points of use,
 - ✓ Availability at points of use either by IT or by dispatch of controlled paper versions
- To ensure that documents remain **legible** and readily **identifiable**,
 - ✓ Legibility - change of IT systems!

Control of Documents and Records (3)

- To ensure that documents of **external** origin determined by the organization to be necessary for the planning and the operation of the quality management system are identified and their distribution controlled, and
 - ✓ E.g. a list of external documents; keep them up to date!
- To prevent the unintended use of **obsolete documents**, and to apply suitable identification to them if they are retained for any purpose.
 - ✓ Collect earlier versions of documents

Control of Documents and Records (4)

4.2.4 Control of records

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

- ✓ where are records kept for how long?
- ✓ Who may access records?
- ✓ How are documents destructed after storage?

Records shall remain legible, readily identifiable and retrievable.

Control of Documents and Records (5)

Aims for the workshop:

- Establish a procedure for control of documents and records
- Establish a list of documents and a list of records

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Improvement

8.5.1 Continual Improvement

The organization shall improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action

The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

Improvement (2)

A documented procedure shall be established to define requirements for

- **Reviewing** nonconformities (including customer complaints),
 - ✓ What action has to be taken by personnel to report a nonconformity? E.g. report form
 - ✓ Who collects nonconformity reports and dispatches them to the appropriate responsible person?
- Determining the **causes** of nonconformities
 - ✓ Who determines the causes of nonconformities?
- Evaluating the need for **action** to ensure that nonconformities do not recur
 - ✓ Who evaluates the action?

Improvement (3)

- Determining and implementing **action** needed
 - ✓ What action has to be taken to prevent recurrence? E.g. change of an operation procedure, educative action, ...
- **Records** of the results of action taken, and
 - ✓ Describe the action taken
- Reviewing the **effectiveness** of the corrective action taken.
 - ✓ Review whether the corrective action will prevent recurrence of the nonconformity

Improvement (4)

8.5.3 Preventive action

The organization shall determine action to **eliminate** the causes of potential nonconformities in order to **prevent** their occurrence.

Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

- **Determining** potential nonconformities and their causes
- **Evaluating** the need for action to prevent occurrence of nonconformities

Improvement (5)

- Determining and implementing **action** needed
 - **Records** of results of action taken, and
 - **Reviewing** the effectiveness of the preventive action taken
- ✓ Same workflow as in corrective actions!

Improvement (6)

Aims for the workshop:

- Establish a procedure for continuous improvement
- Establish a form to report and process nonconformities and preventive actions

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Management process

5.1 Management commitment

Top management shall provide evidence of its **commitment** to the development and implementation of the quality management system and continually improving its effectiveness by

- Communicating to the organization the importance of meeting **customer** as well as **statutory** and **regulatory requirements**,
- Establishing the **quality policy**,
- Ensuring that **quality objectives** are established,
- Conducting **management reviews**, and
- Ensuring the **availability of resources**.

✓ Written in e.g. quality policy or quality management manual.

Management process (2)

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of customer satisfaction.

- ✓ E.g. Customer polls

Management process (3)

5.3 Quality policy

Top management shall ensure that the quality policy

- Is appropriate to the purpose of the organization,
- Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system
- Provides a framework for establishing and reviewing quality objectives
- Is communicated and understood within the organization
- Is reviewed for continuing suitability

Management process (4)

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established and relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

- ✓ List customer, statutory and regulatory quality objectives in a measurable manner and declare them as aims for a working period.

Management process (5)

5.4.2 Quality management system planning

Top management shall ensure that

- The planning of the quality management system is carried out in order to meet the requirements as well as the quality objectives, and
- The integrity of the quality management is maintained when changes to the quality management system are planned and implemented.

Management process (6)

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

- ✓ Define responsibilities in an organization chart and detail responsibilities in job descriptions.

Management process (7)

5.5.2 Management representative

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes

- Ensuring that processes needed for the quality management system are established, implemented and maintained,
- Reporting to top management on the performance of the quality management system and any need for improvement, and
- Ensuring the promotion of awareness of customer requirements throughout the organization.

✓ Appoint a member of top management who is responsible for quality management.

Management process (8)

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

- ✓ Declare the internal communication, e.g. reporting, meetings, informal meetings and their documentation

Management process (9)

5.6 Management review

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained.

✓ Details ...

Management process (10)

5.6.2 Review input

The input to management review shall include information on

- Results of audits (internal, regulatory, ...),
- Customer feedback (polls, complaints, ...),
- Process performance and product conformity (ratios, ...)
- Status of preventive and corrective actions,
- Follow-up actions from previous management reviews,
- Changes that could affect the quality management system, and
- Recommendations for improvement.

Management process (11)

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

- Improvement of the effectiveness of the quality management system and its processes,
- Improvement of product related to customer requirements, and
- Resource needs.

Management process (12)

Aims for the workshop:

- Write a quality policy including top management commitment to quality management and the aim of customer satisfaction
- Establish a list of measurable quality objectives
- Establish an organization chart
- Establish a form for quality management review

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Briefing for workshops

Group 1 - Training, Competence and Awareness

- Establish a procedure for personnel training
- Define roles in your organization and establish job descriptions
- Establish a checklist for training of new personnel
- Establish an annual education plan for personnel

- Prepare a presentation of your results
- Cross-check with other groups
- Have fun and good results!

Briefing for workshops

Training, Competence and Awareness

1. Analysis of needs, skills, gaps
2. Planning, budgeting, selection of providers
3. Agreements, realization
4. Evaluation of benefits
5. Review of coverage of the needs

Briefing for workshops

Group 2 - Control of Documents and Records

- Establish a procedure for control of documents and records
- Establish a list of documents and a list of records

- Prepare a presentation of your results
- Cross-check with other groups
- Have fun and good results!

Briefing for workshops

Control of Documents

1. Preparation, maintenance
2. Identification, marking, filing & listing
3. Check, approval
4. Release, update
5. Withdrawal, removal, disposal
6. Alteration, check, approval
7. Release, update, withdrawal, removal, saving of original

Briefing for workshops

Control of Records

1. Preparation, filing, identification, listing, cataloguing
2. Approval distribution
3. Filing, storage
4. Definition of retention time
5. Protection, retention
6. disposal

Briefing for workshops

Group 3 - Improvement

- Establish a procedure for continuous improvement
- Establish a form to report and process nonconformities and preventive actions
- Prepare a presentation of your results
- Cross-check with other groups
- Have fun and good results!

Briefing for workshops

Improvement

1. Definition of improvement potentials for the system, the processes, the products, the services, the communication, the information and setting of priorities
2. Consideration of objectives, achieving commitment for those
3. Planning, implementing and monitoring of actions
4. Verification of the achievement of the objectives
5. Defining, initiating, realizing, reviewing of follow-up actions

Briefing for workshops

Group 4 - Management Process

- Write a quality policy including top management commitment to quality management and the aim of customer satisfaction
- Establish an organization chart and a list of measurable quality objectives
- Establish a form for quality management review

- Prepare a presentation of your results
- Cross-check with other groups
- Have fun and good results!

Workshops

Any questions???

Zur Anzeige wird der QuickTime™
Dekompressor „
benötigt.

Ask!

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