QMS/EMS Implementation and Control

TRAINING COURSE

INDUSTRIAL ENGINEERING, QUALITY CONTROL AND MANAGEMENT

Course: QMS/EMS Implementation and Control

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Lecture plan:

Quality management system according to ISO standards

- Quality management includes management methods and analysis techniques whose subject is quality management.

- Quality concepts in organizations are based in principle either on norms and standards (international, national or internal to the company) or on the concept of TQM (Total Quality Management).

- The basic standard is ISO 9001 and it is not a management method, but a standard or norm that serves as a reference model for setting the basic management processes in an organization that continuously contributes to improving the quality of the products or services delivered and customer satisfaction (hence quality management system). It is a process-oriented standard.

- Basic principles, system elements and structure of the standard ISO 9001:2015 in the latest revised version, which is more oriented towards strategic management, requires active identification and management of risks, emphasizes customer orientation and overall practicality with less formal documentation.

Lecture plan:

❖ <u>ISO 9001</u> The International Organization for Standardization (ISO) is a non-governmental international organization, which promulgates international standards, which are adapted to the current market needs and which drive innovation and support when challenges arise, or change is wished.

➢ Its creation was demanded by engineers in 1946 in London and it started to operate in 1947 (ISO, 2020).

➢ In 1987, ISO published the ISO 9000 family, which is a set of quality management system (QMS) standards.

➢ The most common standard of the ISO 9000 family is ISO 9001, which is the only standard of this family that can be certified.

➢ The last (newest) version of ISO 9001 has been released in 2015.

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Lecture plan:

➢ **ISO 9001** establishes the requirements to implement, document, maintain and improve a QMS and it is based on the quality management principles (7), which are implied in ISO 9000 and therefore also in ISO 9001 (2015):

- "Customer focus",
- "Leadership",
- "Engagement of people",
- "Process approach",
- "Improvement",
- "Evidence based decision making"
- "Relationship management".

Quality management principles

Relationship Management

Improvement

Customer Focus

7 QUALITY MANAGMENT Principle

Evidence Based Decision Making

Leadership

Process Approach

Engagement of People

Lecture plan:

Seven Quality Management principles

1. Customer focus (organization depends on its costumers):

• Understanding the needs and expectations of customers

• Ensure that the organization's goals are related to the needs and expectations of customers

• Communicate needs and expectations in whole organization

2. Leadership (establishing strategy and direction of the organization):

• A clear vision of the future of the organization

• Maintain shared values and ethics

• Gain the trust of employees and remove fear

• Provide the necessary resources and education

• Inspire, encourage and recognize employee contributions

Lecture plan:

3. Engagement of people (at all levels):

• Full engagement of people enables the use of their abilities

• Discuss problems and issues openly

• Free transfer of knowledge and experience

4. Process approach (manage activities as a process):

• Defining activities in the process and clear responsibilities

• Focus on improving desired results

• RISK assessment, consequences and impact on customers, suppliers and

other stakeholders

Lecture plan:

5. Improvement (should be a constant goal):

• Equal approach throughout the organization for continuous improvement

• Training employees on methods and tools for continuous improvement

• Recognize and recognize improvements

6. Evidence-based decision making (on data analysis)

• Timeliness and reliability of data and information

• Provide access to data, and analyze data and information

7. Relationship management (Supplier Dependence):

• Pooling expertise and resources with partners

• Selecting key suppliers

• Clear and open communication and sharing of information and plans for the future

Lecture plan:

- ✓ Companies implement ISO 9001 and can decide to certify it.

- ✓ Certification is a process in which a third-party, namely a certification body, audits if the QMS implemented in the organization meets the requirements of the ISO 9001.

- ✓ The audit process is done in accordance to the company who supports the auditors during the on-site audit.

- ✓ If the evaluation is positive, the company receives the certificate which is valid for 3 years.

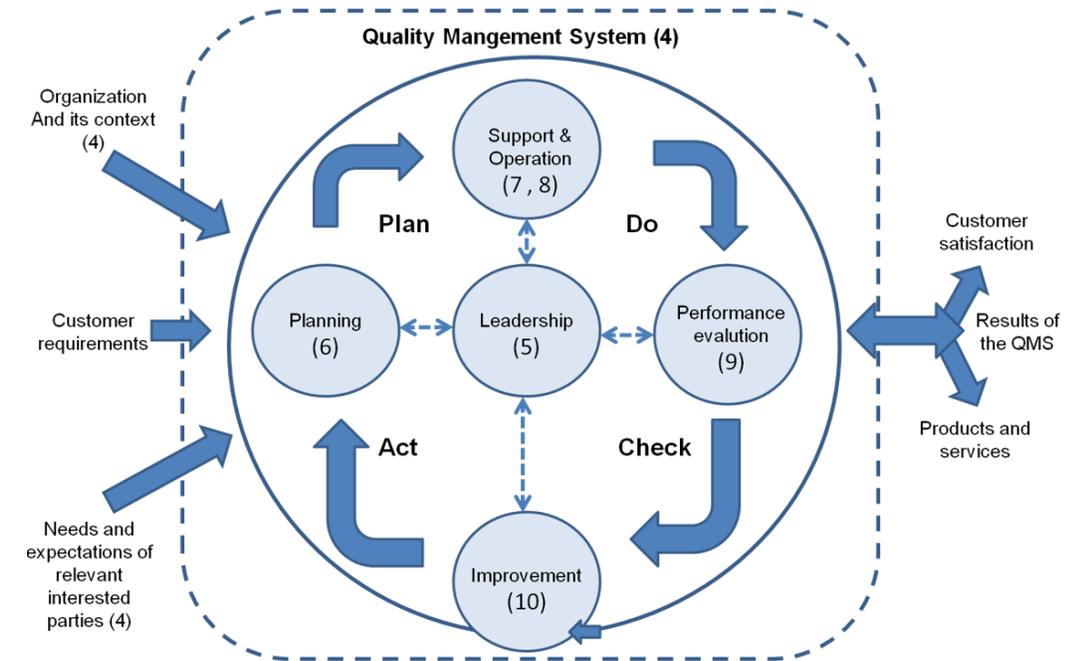- ✓ The ISO 9001 certification supports "knowledge management, customer satisfaction and organizational image"

Figure: High level structure
Process approach ISO
Source: ISO (2015)

Lecture plan:

How do I get started with ISO 9001:2015?

Key tips

- Tip 1 – Define your objectives. Why do you want to implement the standard?

- Tip 2 – Ensure senior management is on board - it is crucial that everyone is supportive of the initiative and its objectives.

- Tip 3 – Identify your organization's key processes for meeting your objectives and customers' needs (within each of these processes, ensure you understand your customers' requirements and can guarantee that these are met).

Lecture plan:

Requirements to Implement a QMS according to ISO 9001:2015

All quality management systems must address a company's unique set of needs; here are

some of general elements that all QMS have in common:

- The creation of a quality manual.

- The existence of quality objectives and policies.

- A set of procedures, records, and instructions about all internal processes, data

  management, quality analysis, improvement opportunities, and customer satisfaction.

Each element is intended to serve a specific purpose that will help to achieve the final goal:

meeting both the organization's and customer's needs - two overarching benefits!

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Lecture plan:

Implementation a Quality Management System

How?

Before establishing of the QMS, several elements must be consider:

At beginning, make sure that your decision to implement a quality management system is a strategic choice only influenced by your needs, objectives, services, and products provided.

After that, here are the basic steps to implement a QMS:

- **Design and Build**: of the structure of the QMS, along with the plan for implementation and all its processes.

- **Deploy**: here, it is important to break each process into multiple sub processes. Also, here is important staff education and documentation, training tools, and metrics.

- **Control and Measure**: These stages are accomplished by systematic, routine audits of implemented QMS.

- **Review and Improve**: in this part deal with the results of the audits is important. The goal is to determine the efficiency and effectiveness of all processes regarding to objectives.

What is a Quality Management System? (globalvision.co)

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