

❖ ISO 9000 Requirements pg 258-270

Matching Game

There are 5 sections. Give classmates statements that describes a major part of each section and have them figure out where their statement fits and then write it under the correct heading on the board or stand in the area of their respective section, then each person takes turn to say what was on their card.

Statements were taken from the book. Locate where they fit, and then find the corresponding heading to stand under. Please state the section and subsection which relates to the statement.

4. QMS

- ❖ The organization shall (a) identify needed processes such as management activities, provision of resources, product realization, and measurement, (b) determine their sequence and interaction, (c) determine criteria and methods for effective operation and control of these processes, (d) ensure the availability of resources and information necessary to support and monitor these processes, (e) monitor, measure and analyze these processes, and (f) implement actions to achieve planned results and continual improvement of these processes.
- ❖ Includes statements of a quality policy & quality objectives, a quality manual, required documented procedures, needed documents to ensure effective planning, operation, and control of processes, and required records. Control of documents by a documented procedure. Records shall be established and maintained to provide evidence of conformity to requirements and effective operation of the QMS.

5. Management Responsibility

- ❖ Top management shall provide evidence of its commitment to the development, implementation and continual improvement of the QMS by communicating the need to meet expectations, establishing a quality policy, ensure that quality objectives are established, conducting management reviews, and ensure availability of resources.
- ❖ Top management shall ensure that customer requirements are determined and met with the aim of enhancing customer satisfaction.
- ❖ Top management shall that the quality policy (a) is appropriate to the organizations purpose or mission, (b) includes a commitment that complies with requirements and

continuous improvements the effectiveness, (c) provides framework for establishing and reviewing the quality objectives, (d) is communicated and understood within the organization, and (e) is reviewed for continuing stability.

- ❖ Top management shall ensure that quality objectives are established at relevant functions and levels within the organization and include product requirements. Shall be measurable and consistent with the quality policy. Top management shall ensure that the planning of the QMS is accomplished in order to meet the requirements.
- ❖ Top management shall ensure that responsibilities and authorities are defined and communicated within the organization. Top management shall appoint a member of management, regardless of his/her other duties, that shall have the responsibility and authority to ensure processes for the QMS is established, implemented and maintained. They will report performance to top management and any need for improvement. Top management shall ensure that appropriate communication channels are established within the organization and that communication takes place regarding the QMS.
- ❖ Top management shall review the QMS at planned intervals to ensure its continuing suitability, adequacy, and effectiveness. Will include Review input and review output.

6. Resource Management

- ❖ The organization shall determine and provide the resources needed to implement, maintain the QMS and continually improve its effectiveness; and to enhance customer satisfaction by meeting customer requirements.
- ❖ Personnel performing work that affects product quality shall be competent on the basis of appropriate education, training, skills, and experience. The organization shall determine the necessary competence for personnel performing work affecting product quality, provide training or take actions to satisfy these needs, evaluate the effectiveness of the actions taken, ensure personnel are aware of relevance and importance of their activities and how they contribute to quality, and maintain records for education, training, skills and experience.
- ❖ The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes buildings, workspace, and associated utilities; process equipments (both hardware and software), and supporting services (such as transport or communication).

- ❖ The organization shall determine and manage the work environment needed to achieve conformity to product requirements. Creation of a suitable work environment can have a positive influence on employee motivation, satisfaction and performance.

7. Product Realization

- ❖ The organization shall plan and develop the processes needed for product realization. It shall be consistent with the requirements of the other processes of QMS.
- ❖ The organization shall determine requirements specified by the customer, requirements not stated by the customer but necessary for specified or intended use, statutory and regulatory requirements related to the product and any additional requirements determined by the organization. The organization shall review the requirements related to the product, as well as, determine and implement effective arrangements for communicating with customers.
- ❖ The organization shall plan and control the design and development of the product. Inputs relating to product requirements shall be determined and records maintained. The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.
- ❖ At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements. Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. Design and development changes shall be identified and records maintained.
- ❖ The organization shall ensure that purchased product conforms to specified purchase requirements. Purchasing information shall describe the product to be purchased. The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.