Specification Document & Requirements

Overview

Document link below contains the ISO 9001:2015 specification requirements.

ISO9001-2015.pdf

Minimum Requirements

Organisation Context

The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

The organization shall monitor and review information about these external and internal issues

Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization’s ability to consistently provide products and
services that meet customer and applicable statutory and regulatory requirements, the organization
shall determine:

- a) the interested parties that are relevant to the quality management system;
- b) the requirements of these interested parties that are relevant to the quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements

Determining the scope of the quality management system

The organization shall determine the boundaries and applicability of the quality management system
to establish its scope

Quality management system and its processes

The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

The organization shall determine the processes needed for the quality management system and their
application throughout the organization, and shall:

- a) determine the inputs required and the outputs expected from these processes;
- b) determine the sequence and interaction of these processes;
- c) determine and apply the criteria and methods (including monitoring, measurements and related
  performance indicators) needed to ensure the effective operation and control of these processes;
- d) determine the resources needed for these processes and ensure their availability;
- e) assign the responsibilities and authorities for these processes;
- f) address the risks and opportunities as determined in accordance with the requirements of 6.1;
- g) evaluate these processes and implement any changes needed to ensure that these processes achieve
  their intended results;
- h) improve the processes and the quality management system.

Leadership and commitment

General

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

- a) taking accountability for the effectiveness of the quality management system;

- b) ensuring that the quality policy and quality objectives are established for the quality management
  system and are compatible with the context and strategic direction of the organization;
- c) ensuring the integration of the quality management system requirements into the organization’s
  business processes;
- d) promoting the use of the process approach and risk-based thinking;
- e) ensuring that the resources needed for the quality management system are available;
- f) communicating the importance of effective quality management and of conforming to the quality
  management system requirements;
- g) ensuring that the quality management system achieves its intended results;
- h) engaging, directing and supporting persons to contribute to the effectiveness of the quality
  management system;
- i) promoting improvement;
- j) supporting other relevant management roles to demonstrate their leadership as it applies to their
  areas of responsibility

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