

Preface

ISO 9001 Standard specifies the requirements of a quality management system (QMS) for organization for delivering products and services with consistent quality to customers and satisfying applicable statutory and regulatory requirements. The QMS is applied by many organizations throughout the world.

Large organizations demand their suppliers to establish and maintain QMS with accreditation to ISO 9001. Government departments specify the accreditation requirement as precondition to participate in their tenders. Hence, it is necessary for all types of organizations to establish QMS conforming to ISO 9001.

Two categories of expertise are required for establishing a practical and effective ISO 9001 QMS. The functioning of organization and the design & manufacturing processes of products should be understood for preparing practical QMS documents. Secondly, the requirements of ISO 9001 should be understood for preparing the documents in accordance with the international standard. This book presents adequate guidance for understanding the requirements of the standard. The requirements are illustrated with examples from industries for unambiguous and clear understanding.

Chapter 1 introduces the internal customer–supplier relationship for understanding quality. The internal customer–supplier concept is regarded by some as one of the most powerful aspects to emerge from total quality management [1]. QMS is introduced using the concept for fulfilling the needs and expectations of internal and end customers with two examples.

The needs and the considerations for establishing the documents of QMS are indicated in Chap. 2. Process approach is one of the seven quality management principles of ISO 9001, and it integrates people with processes to achieve consistent results [2]. The approach is fundamental for preparing QMS documents. Process characterization is illustrated with examples to apply the process approach for preparing the documents. Sequence of processes, interactions of the processes and the categories of QMS documents are also explained.

Chapter 3 explains the management processes of ISO 9001. Guidance for identifying the internal and external issues that are relevant to organization and monitoring the issues is presented. Guidance is also provided for monitoring the

needs and expectations of interested parties to provide products meeting customer requirements. The requirements for determining the scope and establishing the QMS of organization, leadership and planning are explained. Planning actions to address risks and opportunities and integrating the actions with QMS processes are illustrated for three operational processes.

Resources, monitoring and measuring resources, organizational knowledge, communication and documented information are grouped as support processes, and they are required for the operation of QMS processes. The requirements of the support processes are explained in Chap. 4.

Operational processes contribute significantly to the growth of organization. Planning, understanding customer requirements for products, design & development, control of external providers and production are the operational processes. The requirements of the operational processes and other related processes are explained with practical examples for deeper understanding in Chap. 5. Adequate information is provided for the processes related to the operational processes, and the processes are identification and traceability, customer property, preservation, post-delivery activities, control of changes, release of products and nonconformity control.

Chapter 6 describes the requirements of evaluating and improving the QMS of organization. Monitoring, measurement, analysis, evaluation, customer satisfaction internal audit and management review are explained, and examples are provided where required. Key performance indicators are suggested for measuring the performance of QMS processes.

The requirements of QMS should be amalgamated, i.e. integrated with the operational processes of the organization from the receipt of customer requirements to the delivery of products to customers for achieving and sustaining business growth. Integrating QMS requirements with ERP or other software is the most effective method, and it provides valuable benefits to organization. Software system engineering is briefly introduced. Requirements analysis with abbreviated activity diagrams and user acceptance testing is presented for providing inputs for developing software for the control of measuring resources in Chap. 7. The methods of integrating the QMS requirements with ERP software are illustrated for three operational processes in Chap. 8.

Thirukkural is an Indian classic literature in Tamil, one of the ancient languages of India. The classic literature is generally accepted as more than 2000 years old. The literature is secular, and some of the earliest translations in French (1848 and 1889), German (1856) and English (1886) indicate its universal acceptance. Thirukkural contains 1330 verses (kurals in Tamil). A kural is a couplet containing a complete and striking idea expressed in a refined and intricate metre [3]. Applying the ideas of the kurals for planning the actions to address risks and opportunities in QMS processes, design & development and production processes is presented in Chap. 9.

References

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3. Rev. Dr. Pope GU (1886) The ‘Sacred’ Kurraḷ of Tiruvalluva-Nayanar, with introduction, Grammer, Translation & Notes. W.H.Allen & Co., London



<http://www.springer.com/978-3-319-54382-6>

ISO 9001 Quality Management Systems

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2017, XXI, 160 p. 35 illus., Hardcover

ISBN: 978-3-319-54382-6