Chapter 2
Establishing ISO 9001 QMS Documentation

Abstract Every organization, however small it is, practices the requirements of a documented quality management system (QMS) for processing customer orders. The existing practices and the documents of the organization are improved and aligned to the requirements of ISO 9001 for establishing QMS. The benefits and the considerations for establishing the QMS are presented. Process characterization, sequence of processes and their interactions are fundamental for establishing QMS and they are illustrated with examples. Expertise required for preparing QMS documents and the needs for having quality manual for organization are also presented.

2.1 Documented QMS

Documentation refers to writing procedures or instructions for carrying out the processes of organization. Every organization, small or large, practices the requirements of a documented quality management system (QMS) for processing customer orders. Quotes for customer enquiries, order acceptance, availability of controlled engineering drawings, purchase orders on suppliers with appropriate purchasing information, identification system for the storage of products and displaying work instructions in manufacturing areas are some of the examples of practicing the requirements of documented QMS. The existing process procedures and the documents of organization are improved and aligned to the requirements of ISO 9001 for establishing QMS for the organization. The needs and the basic considerations for preparing QMS documents are explained.

2.1.1 Needs for Documentation

ISO 9001 QMS describes the minimum level of documentation for the QMS of organization. The needs for preparing the documentation are shown in Fig. 2.1 and they are:

D. Natarajan, *ISO 9001 Quality Management Systems*,
Management and Industrial Engineering, DOI 10.1007/978-3-319-54383-3_2

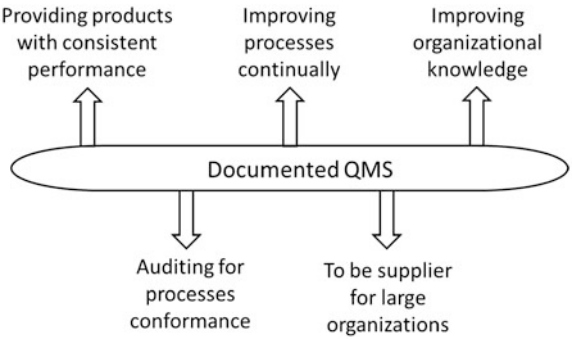

Fig. 2.1 Needs for QMS documentation

(i) To provide products with consistent performance to customers.
(ii) To improve processes continually.
(iii) To convert the expertise of individuals into organizational knowledge.
(iv) To conduct audits of QMS processes for conformance.
(v) To be a supplier for large organizations.

2.1.2 Basic Considerations

QMS documentation is prepared to comply with the requirements of ISO 9001 and to achieve the objectives of organization. Other considerations for preparing the documentation are shown in Fig. 2.2 and they are:

(i) Optimum level of documentation:
Optimum level of documentation is planned considering the size of organization, the loss that would occur if processes were to fail and the competence of personnel.
(ii) Maintaining existing rhythm:
Usually, QMS documentation is prepared for existing organization. The organization might have proven methods of managing processes to satisfy

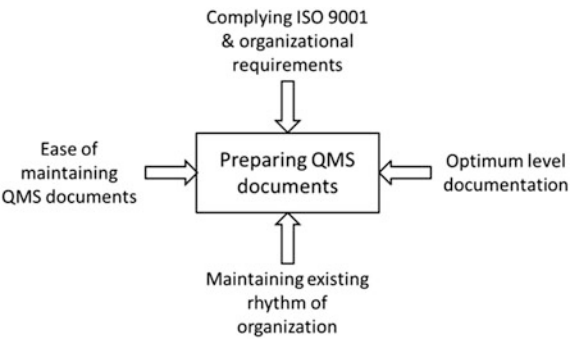

Fig. 2.2 Considerations for preparing QMS documents

customers. The existing rhythm in managing processes should be maintained to the extent feasible in developing the QMS documentation as it provides comfort for understanding the documents and implementation. Innovative efforts are applied to avoid or minimize drastic changes in the existing methods as drastic changes might lead to quality problems resulting in customer dissatisfaction.

(iii) Ease of maintaining QMS documents:
QMS documents are amended as required by various corrective, preventive and improvement actions during the implementation of the QMS. Hence, they are organized for maintaining the documents easily. Needs to amend too many QMS documents for one action are avoided.

2.2 Process Approach

Process approach is one of the seven quality management principles of ISO 9001 and it integrates people with processes to achieve consistent results [1]. The approach is fundamental for preparing QMS documents. Process characterization is illustrated with examples to apply the process approach for preparing the documents.

2.2.1 Defining Process Characterization

Process characterization is defined as identifying elements and understanding their linkages for operations. The requirements relevant to processes are considered for characterizing the processes. The elements are listed below and the linkage between the elements is shown in Fig. 2.3:

(i) Inputs
(ii) Process procedure with acceptance criteria
(iii) Outputs
(iv) Monitoring and measurement:
Monitoring and measurement activities are performed for controlling and improving processes. Additional information is provided for understanding monitoring and measurement.

2.2.2 Monitoring and Measurement

Monitoring is keeping track of a requirement and measurement is ascertaining (measuring) the level of achieving the requirement using gauges or test equipment or software. The requirement could be temperature, product delivery performance, time to carry out a process, etc. Generally, the requirements are monitored and

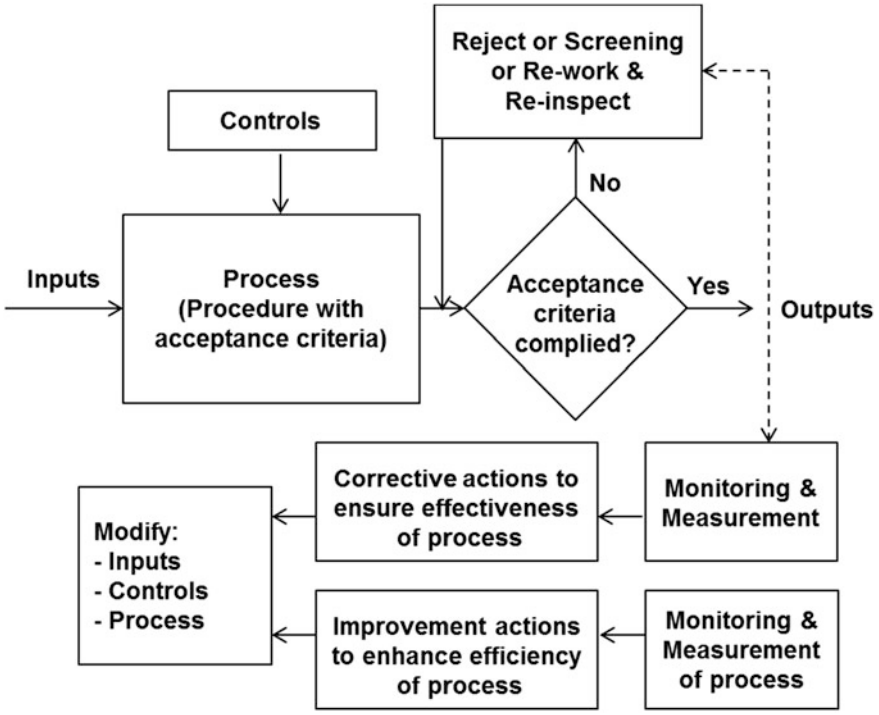

Fig. 2.3 Characterizing QMS process

measured simultaneously. Monitoring and measurement requirements are applied for control purpose, achieving intended process outputs (ensuring process effectiveness) and improving process (efficiency) [2].

2.2.2.1 Control Purposes

A sequence of operations is performed for carrying out a process. The relevant parameters of the operations are determined, monitored and measured for control purposes to minimize variations in the planned outputs of the process. The monitoring and measurement check points for control purposes are specific to process needs. Monitoring and measurement for control purposes are generally applicable for production processes.

2.2.2.2 Ensuring Process Effectiveness

A process is considered effective if the planned outputs of the process are achieved with consistent quality. Failures (defects) might be observed by process owners when

carrying out processes or reported by other internal customers and end customers. The outputs of processes and the reported failures are monitored and measured using appropriate performance indicators. Corrective actions are implemented for the failures to ensure the effectiveness of processes. Monitoring and measurement for ensuring process effectiveness are explained in greater details in Sect. 6.2.

2.2.2.3 Improving Process Efficiency

Improving process efficiency is basically minimizing cost and time for carrying out processes. It is usually decided in management reviews. Process owners decide the methods of monitoring and measurement for improving the efficiency of processes.

2.3 Illustrating Process Characterization

Process characterization is well understood for product related production processes. Consider the reflow soldering process for mounting components on printed circuit boards (PCBs). The soldering process is characterized by inputs, process procedure with acceptance criteria and outputs. Monitoring and measurement are integrated with the process procedure. The elements of characterizing reflow soldering process are explained.

2.3.1 Inputs

Inputs for a process are the outputs of its previous process and the resources required for carrying out the process. Planning is the process previous to the reflow soldering process and it provides the inputs for reflow soldering. The inputs from planning are PCBs and surface mount components. The resources for carrying out the soldering process are reflow soldering equipment, tools, consumables, ultrasonic solvent bath for cleaning assembled PCBs and inspection equipment.

2.3.2 Process Procedure with Acceptance Criteria

Process procedure describes the steps for carrying out the reflow soldering process. The manufacturers of reflow soldering equipment describe the process procedure in detail. Baking PCBs, application of solder paste to pads, placing the parts and reflow soldering using the recommended profile are the major steps of the procedure [3]. The steps are described in the process procedure.

Acceptance criteria are specified in the process procedure to accept or rework or reject the assembled PCBs. Cleanliness and uniform solder joints are examples of acceptance criteria [3]. The PCBs are visually inspected after soldering and cleaning using the specified inspection equipment. In-process visual inspection for PCBs after applying solder paste to pads could also be specified in the process procedure. Quality needs of the internal customer of reflow soldering process are addressed in the process procedure.

2.3.3 Quality Needs of Internal Customer

The assembled PCBs after reflow soldering are delivered to the internal customer for electrical testing of the PCBs. Some of the critical quality needs of the internal customer are that CMOS components should be free from ESD related damages and the electrical performance of chip components should not have been degraded due to thermal shock in solvent cleaning process. The quality needs of the internal customer are addressed in the process procedure for reflow soldering process. Precautions to prevent ESD damages and for solvent cleaning of assembled PCBs are specified in the process procedure.

2.3.4 Monitoring and Measurement

The reflow soldering process parameters are monitored and measured to control the process for maximizing the output of acceptable assembled PCBs without rework i.e. for improving first time yield. Examples of process parameters are PCB baking temperature, soldering profile and the status of cleaning solvent. The requirements of monitoring and measuring process parameters for control purposes are addressed in process procedure.

The soldering defects observed during the inspection of assembled PCBs and those reported by the internal customers are monitored and measured. The defects are analyzed to identify the root causes of the defects and corrective actions are implemented to ensure process effectiveness. Improving process efficiency (minimizing cost and time for reflow soldering) through monitoring and measurement is a technical assignment and it is not explained.

2.3.5 Outputs

The outputs of reflow soldering process are assembled PCBs for the next internal customer and quality records. The outputs are:

(i) Acceptable assembled PCBs without visual defects and electrical damages to parts.
(ii) Quality records to provide evidences for carrying out the process:

- In-process and final inspection records
- Monitoring and measurement results as specified in the process procedure.

2.4 Process Approach for Controlling Engineering Documents

Process characterization is explained addressing the requirements of engineering documents. Creating, updating and controlling are the requirements the documents. Adequate information is provided in Sect. 4.8 for preparing the quality procedure addressing the requirements of engineering documents. The requirements that are unique for the quality procedure are presented.

2.4.1 Inputs and Outputs

The design and development outputs of product are the inputs for creating engineering documents. The resources are software drafting systems. The requirements of the quality procedure are implemented is applied during the preparation of the documents. The outputs of the quality procedure are:

(i) Approved engineering documents
(ii) Master list of engineering documents
(iii) Distribution or access list for the documents
(iv) Change control information for updated engineering documents
(v) Retaining obsolete engineering documents with suitable identification as specified in process procedure.

2.4.2 Quality Needs of Customers and Acceptance Criteria

Process procedure should address the quality needs of internal and end customers. Although the design team of products controls engineering documents, they are not the users of the documents. End customers, production departments, external providers of products and quality assurance are the users of the documents. Avoiding contradicting engineering information in documents and providing information for achieving the planned results of production processes are examples of the quality

needs of the customers. The quality needs of the customers should be addressed in the quality procedure, as appropriate.

Engineering documents are reviewed before approval. The review requirements are part of the quality procedure and they are listed in Sect. 4.8.1. The review requirements serve as acceptance criteria and controls for the process procedure.

2.4.3 Monitoring and Measurement

Errors in engineering documents might be reported by internal and end customers. Design team reviews the errors and updates relevant engineering documents. The number of updates indicates the effectiveness of preparing and reviewing engineering documents by design team. Monitoring and measurement for minimizing time (improving process efficiency) for preparing engineering documents are decided in management reviews.

2.5 QMS Processes

QMS processes are those specified in ISO 9001 and those determined by organization for their QMS. ISO 9001 processes are related to management, support, operation, performance evaluation and improvement. Examples of the additional processes determined by organization are:

(i) Failure mode and effects analysis for product design
(ii) Statistical techniques for manufacturing
(iii) Reward schemes for improving processes continually
(iv) Periodical reviews of customer orders to satisfy their requirements
(v) Additional controls for contract manufacturing

QMS processes are characterized and documented (Sects. 2.3 and 2.4). The sequence of the processes and their interactions are also determined and documented.

2.5.1 Sequence and Interaction of QMS Processes

Sequence of processes is the order of implementing the processes for achieving planned results. Most of the processes receive inputs from many other processes and their outputs are used by multiple processes during implementation of the processes. In other words, there is interaction or linkage between the processes. Sequence and interaction of processes are illustrated with an example.

2.5.1.1 Illustration

A simplified process flow diagram showing the sequence and interactions of management, support and some of the product related processes of RF Filters are shown in Fig. 2.4. The sequence of production processes are in series. It can be seen in the figure that the process, Tuning and Testing for RF Filters, interacts with management, support and product related processes. Additional information for planning and establishing interaction between processes is presented for ensuring process effectiveness.

2.5.1.2 Additional Information for Process Interactions

Timing and sequence of interacting processes should be considered for determining the processes [4]. As an example, consider ultrasonic cleaning process that interacts with RF Filter Assembly process. The cleaning process is not shown in Fig. 2.4. The ultrasonic solvent cleaning bath is maintained at appropriate intervals for removing the flux residues of PCBs effectively. The timing of interaction for maintaining the bath is decided considering the volume of PCBs in the assembly process.

Planning process interacts with many other processes such as marketing, design, external providers, verification of externally provided products and production processes. The sequence of receiving inputs from the interacting processes are determined and documented for ensuring the effectiveness of planning process.

2.6 QMS Documents

QMS documentation is usually developed as multi-level documents to protect the confidentiality of engineering and other documents of organization. Documentation begins with establishing product related engineering documents and it is continued with the preparation of quality procedures for the processes of organization. The approach ensures clarity and continuity in the presentation of QMS documents. Both

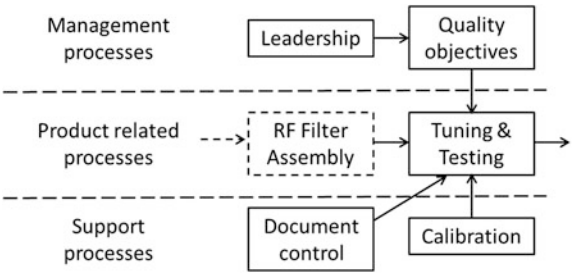

Fig. 2.4 Simplified sequence and interaction of processes for RF filters

upward and downward linkages are ensured in the preparation of the documents. Although quality manual document is not mentioned in ISO 9001, it is necessary for an organization. The reasons for preparing the document are explained.

2.6.1 Quality Manual

Quality manual is a document that presents the overview of ISO 9001 QMS of organization. The quality manual is required for:

(i) Quality manual presents not only the overview of ISO 9001 QMS but also addresses business capabilities and briefly other abilities to achieve the planned results of QMS, thus supporting the business needs of organization.
(ii) Potential customers would like to understand the QMS of organization and plan assessment audit prior to visiting the organization. Quality manual supports the planning of assessment audit. Similar requirement might be expressed by certification bodies before registration audits.
(iii) All the clauses of ISO 9001 should be addressed in the QMS documents of organization. Documented information (quality procedures) is not needed for all the processes of ISO 9001. Quality manual is the means to ensure that all the clauses of ISO 9001 are addressed.

It is recommended that the quality manual is preferably prepared after the trial implementation of the QMS of organization and updating the documents based on the observed non-conformities. The approach ensures clarity in quality manual.

2.6.2 Expertise for Preparing QMS Documents

Two categories of expertise are required for preparing practical QMS documents. The requirements of expertise are shown in Fig. 2.5 and the requirements are:

(i) Core expertise:
ISO 9001 QMS does not specify stand-alone requirements. The requirements of the QMS should be are appropriately integrated with the operational process

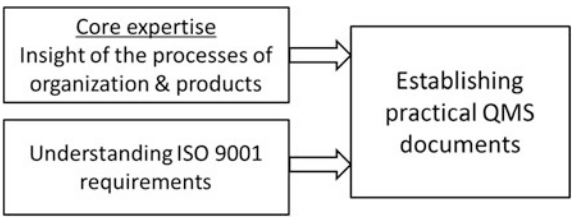

Fig. 2.5 Expertise for establishing QMS documents

of organization. The insight into the functioning of organization and the design and manufacturing processes of products are the core expertise required for preparing practical QMS documents for organization.

(ii) Understanding ISO 9001:
Understanding the requirements of ISO 9001 is essential for preparing QMS documents in accordance with the international standard. The requirements of ISO 9001 are explained in the next four chapters. Adequate guidance and examples from industries are provided to facilitate the understanding the requirements.

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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