

Type Your Company Name Here

Quality Manual

ISO 9001:2008

Street Address

City, State Zip

*This manual is to be used as a template in developing your ISO 9001 Quality Manual. Review the text; replace text to match your quality system requirements. At a minimum, the blue text should be replaced with your information. "***Your Company***" indicates that you should use your company name in that spot. Replace the ISO 9000 Store name and logo with your company name and logo.



Introduction

Your Company developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The Quality Management System of *Your Company* meets the requirements of the international standard ISO 9001:2008). This system addresses the design, development, production, installation, and servicing of the company's products.

The manual is divided into eight sections that correlate to the Quality Management System sections of ISO 9001:2008. Each section begins with a policy statement expressing *Your Company's* obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

President: _____

NOTES: DELETE AFTER EACH TASK IS COMPLETED.

- **USE REPLACE FUNCTION – ENTER “YOUR COMPANY” IN FIND SPACE, ENTER YOUR COMPANY NAME IN REPLACE SPACE – SYSTEM SHOULD MAKE CHANGES THROUGHOUT THE ENTIRE DOCUMENT.**
- **(IF ANY OTHER INFORMATION IS AVAILABLE, THAT WOULD FURTHER ENHANCE THE COMPANY INTRODUCTION, PREFERABLY ELECTRONICALLY, THIS IS THE AREA IN THE MANUAL TO INSERT THAT INFORMATION)**



Section 7: Product Realization



7.1 Planning of product realization

Quality planning is required before new products or processes are implemented. The quality planning may take place as a design project, or according to the Planning of Product Realization procedure (MP-710). During this planning, management or assigned personnel identify:

- The quality objectives and requirements for the product,
- Processes, documentation and resources required
- Verification, validation, monitoring, inspection and test requirements, and
- Criteria for product acceptance

The output of quality planning includes documented quality plans, processes, procedures and design outputs.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

Your Company determines customer requirements before acceptance of an order. Customer requirements include those:

- Requested by the customer
- Required for delivery and post-delivery activities
- Not stated by the customer but necessary for specified use or known and intended use
- Statutory and regulatory requirements applicable to the product
- Additional requirements determined by *Your Company*

Customer requirements are determined according to the Customer Related Processes Procedure. (SP-720)

7.2.2 Review of requirements related to the product

Your Company has a process in place for the review of requirements related to the product (SP-720). The review is conducted before the order is accepted. The process ensures that:

- Product requirements are defined



- Contract or order requirements differing from those previously expressed are resolved
- *Your Company* has the ability to meet the defined requirements
- Records are maintained showing the results of the review and any actions arising from the review
- Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance
- When product requirements are changed, *Your Company* communicates changes to relevant personnel and amends relevant documents

7.2.3 Customer communication

Your Company has implemented an effective procedure (SP-720) for communicating with customers in relation to:

- Product Information
- Enquiries, contracts and order handling, including amendments
- Customer Feedback, including customer complaints

7.3 Design and Development

7.3.1 Design and development planning

The design and development procedure (EP-730) outlines the process for controlling the design and development process. The *R&D Department* plans design and development according to this procedure. The design plan includes:

- Design and development stages
- Required design reviews
- Verification and validation methods appropriate to each design and development stage
- Responsibilities and authorities for design and development
- Identification of the technical interfaces required for the project
- Updating of the design plan as the project progresses



7.3.2 Design and development inputs

Inputs relating to product requirements are determined and documented according to the Design and Development procedure (EP-730). All inputs are reviewed for adequacy and completeness, and to resolve any ambiguous inputs. Inputs include:

- Functional and performance requirements
- Applicable statutory and regulatory requirements
- Where applicable, information derived from previous similar designs
- Other requirements essential for design and development

7.3.3 Design and development outputs

Outputs of design and development are documented according to the Design and Development Procedure (EP-730). They are documented in a format that enables verification against the inputs, and are approved prior to release. Outputs:

- Meet the input requirements
- Provide appropriate information for purchasing, production and for service provision
- Contain or reference product acceptance criteria
- Specify the characteristics of the product that are essential for its safe and proper use.

7.3.4 Design and development review

The design plan specifies suitable stages of the project to conduct design and development review. Reviews take place according to the design and development procedure; results of design review are recorded in minutes of the design review meetings which are maintained as a quality record. Design reviews:

- Evaluate the results of design and development activities and determine if they fulfill requirements
- Identify any problems and propose necessary actions
- Include representatives of functions concerned with the design and development stage being reviewed



7.3.5 Design and development verification

Design verification is planned and performed to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and any necessary actions are maintained according to the Design and Development procedure (EP-730).

7.3.6 Design and development validation

Design and development validation is performed according to the design plan to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application. Validation is completed prior to delivery whenever practicable. Records of the validation activities are maintained according to the design and development procedure.

7.3.7 Control of design and development changes

The design and development procedure defines a process for identifying, recording, verifying, validating and approving design changes. The review of design and development changes includes an evaluation of the effect of the changes on constituent parts and delivered product. Records are maintained to show the results of the review and any necessary actions identified during the review.

7.4 Purchasing

7.4.1 Purchasing process

A documented procedure (AP-740) is followed to ensure that purchased product conforms to the specified purchase requirements. The procedure outlines the extent of control required for suppliers. Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in the procedure. Criteria for selection, evaluation and re-evaluation are documented in the procedure. Records of the evaluation and any necessary actions are maintained as quality records.

7.4.2 Purchasing information

Purchasing information describes the product to be purchased, including where appropriate:

- Requirements for approval of product, processes and equipment
- Requirements for qualification of personnel
- Quality management system requirements

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.



7.4.3 Verification of purchased product

The Purchasing procedure (AP-740) describes the process used to verify that purchased product meets specified purchase requirements. If *Your Company* or the customer will perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information.

7.5 Production and Service Provision

7.5.1 Control of production and service provision

Your Company plans and carries out production and service provision under controlled conditions according to documented procedure (MP-750). Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product
- The availability of work instructions
- The use of suitable equipment
- The availability and use of monitoring and measuring devices
- The implementation of monitoring and measurement
- The implementation of release, delivery and post-delivery activities

7.5.2 Validation of processes for production and service provision

Your Company validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results.

Your Company has documented the process for validation including:

- Defined criteria for review and approval of the processes
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures
- Requirements for records
- Revalidation