

Quality Manual



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Quality Manual include

scope of the Quality Management System,
including objectives and a declaration for any
exclusions (see 1.2).

references to documented procedures
established for the Quality Management System,
and

description of the interaction between the
processes of the Quality Management System.

INSTRUCTIONS FOR USE (DELETE THIS SECTION AFTER COMPLETING THE MANUAL)

Review all highlighted sections and edit to suit your company's needs. Delete any helpful instructions provided within the manual. Remove all yellow highlights while keeping necessary text before finalizing the manual.

Use Microsoft Word's "Find and Replace" function to replace the words "our company" with your company's name. This gives ownership for the ISO program.

The file name includes the document revision and is shown in the footer of this file. By changing the revision level in the document name, you are automatically changing the revision level in the footer. This is a very simple way to maintain document revision levels (reference Section 4.2.3 for more details.)

Instructions: To update the Table of Contents, click on the Table, press F9 and select "Update page numbers only."

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1 Scope

1.1 General

Our company has developed and implemented the Quality Management System (QMS) described in this manual to help our organization demonstrate its ability to consistently provide products/services that meet customer and applicable regulatory requirements, and operate with increased effectiveness and efficiency with the overall goal of enhancing customer satisfaction.

Our QMS utilizes the process approach and quality management principles contained in the ISO 9001:2008 international standard to enhance our ability to consistently improve.

1.2 Application

Our QMS complies with all applicable regulatory requirements of ISO 9001:2008 and encompasses all operations at the following location(s):

Company Name
Street Address
City, State, Zip Code

The following table identifies ISO 9001:2008 requirements not applicable to our organization and provides a brief justification for their exclusion from the scope of our QMS.

Instructions: This table allows you to identify exclusions to subclauses contained within Section 7 of the standard. If an exclusion does not apply to your company, delete the appropriate row(s) from the table. To learn more about the specifics of each topic and to help you determine if an exclusion applies to your company, please refer to the specific section in this Quality Manual.

ISO 9001:2008 Requirements EXCLUSION TABLE

Clause or Sub-clause	Exclusion	Justification
7.3	Design and Development	Our company receives orders from customers to manufacture customer-specific products. Our company does not market any off-the shelf company-owned designs.
7.5.2	Production Process Validation	Our company does not have any processes in which the results cannot be verified by subsequent monitoring or measurement.

2 Reference Documents

The following external documents contain provisions, which through reference in this manual, constitute provisions of our QMS:

ISO 9000:2005, Quality Management Systems – Fundamentals and vocabulary

ISO 9001:2008, Quality Management Systems – Requirements

Section 10 of this manual shows all of our company's procedures and the sequence and interaction between them.

The latest edition of each referenced document applies. Section 4.2.3 defines our policy and procedures governing the control of these and other QMS documents. Note: documents are referenced throughout this manual by document number.

3 Terms and Definitions

Our QMS uses the same interpretation of terms, vocabulary and definitions given in ISO 9000:2005.

4 Quality Management System

4.1 General Requirements

Our company has established, documented, implemented and is maintaining a Quality Management System. We are continually improving its effectiveness in accordance with the requirements of ISO 9001:2008.

Our company:

- a) has determined the processes needed for the Quality Management System and their application, including the sequence and interaction of these processes,
- b) has determined the sequence and interaction of these processes,
- c) has determined the criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensures the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitors, measures, where applicable, and analyzes these processes, and
- f) implements actions necessary to achieve planned results and continual improvement of these processes.

These processes are managed in accordance with the requirements of this manual and the ISO 9001:2008 International Standard.

Outsourced processes that affect product conformity are controlled utilizing Contracts, Purchase Orders and Inspection as defined in Section 7.4 and its subclauses. Our company takes responsibility for conformity to all customer, statutory and regulatory requirements, even when processes are outsourced. The type and extent of control is influenced by factors such as:

- a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,
- b) the degree to which the control for the process is shared,
- c) the capability of achieving the necessary control through the application of 7.4.

NOTE 1 Processes needed for the Quality Management System referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.

4.2 Documentation Requirements

4.2.1 General

The Quality Management System shall include:

- a) documented statements of a quality policy and quality objectives,
- b) a quality manual,
- c) documented procedures required by the ISO 9001:2008 International Standard and
- d) documented records, where necessary, to ensure the effective planning, operation and control of processes.

4.2.2 Quality Manual

The Quality Manual shall be maintained as the company's Quality Manual. It includes:

- a) the scope of the Quality Management System, including details of and justification for any exclusions (see Section 11)
- b) references to the documented procedures established for the Quality Management System (see Section 11)
- c) a description of the interaction between the processes of the Quality Management System (see Section 10.)

4.2.3 Control of Documents

Documents required by the Quality Management System are controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

Our company has a documented procedure that defines the controls needed

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,

- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) to ensure that documents of external origin that are necessary for the planning and operation of the Quality Management System are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of Records

Our company keeps records to provide evidence of conformity to requirements and of the effective operation of the Quality Management System. The records are controlled.

Our company has a documented procedure to determine controls needed for the identification, storage, protection, retrieval, disposition of records. Records are legible, readily identifiable and available.

5. Management Responsibility

5.1 Management Commitment

Top management is committed to the development, implementation and maintenance of the Quality Management System and to continually improving its effectiveness. Management:

- a) determines the needs and expectations of customers as well as statutory and regulatory requirements,
- b) has established the quality policy and reviews the quality policy during management review,
- c) ensures quality objectives are established and measured,
- d) conducts management review, and
- e) ensures the availability of resources.

5.2 Customer Focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see Sections 7.2.1 and 8.2.1.)

Our Quality Policy articulates our commitment to our customers. Customer complaints and other feedback are monitored to measure and identify opportunities for improvement (see Section 8.2.1.) We continually look for other ways to interact directly with individual customers to ensure are meeting their unique needs and expectations.

Instructions: If your company doesn't have a web presence, delete the following paragraph.

Additionally, we have established an interactive website to provide our customers with quick access to information and points of contact within our organization regarding our products (see Section 7.2.3.)

5.3 Quality Policy

Top management has established a Quality Policy that:

- a) describes our company's core competency,
- b) includes a commitment to comply with requirements and continually improve the effectiveness of our Quality Management System and
- c) provides a framework for establishing and reviewing Quality Objectives.

The Quality Policy is communicated and understood within the organization, and is reviewed for continuing suitability during Management Review.

5.4 Planning

5.4.1 Quality Objectives

Quality Objectives are established at important functions and levels within the organization. The Quality Objectives are measured and are consistent with the Quality Policy. Objectives are developed in accordance with the company's strategy to support the main Quality Objective of the company.

5.4.2 Quality Management System Planning

- a) the Quality Management System is carried out in order to meet the requirements specified in the Quality Objectives and
- b) the integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Top management has defined responsibilities and authorities and communicated them within the organization.

Instructions: Review the following responsibilities and modify to meet your company's operations. Un-highlighted references related to the Quality Management Representative and Top Management must not change.

The President sets direction and ensures the success of our business through the clear definition and communication of QMS responsibilities and authorities. Other members of Top Management include: the CFO and the Vice President of Sales Engineering.

With respect to the QMS, the Quality Management Representative is included as a member of Top Management. The interrelationship of Top Management and other key personnel is depicted in our company's Organizational Chart (see Section 9.)

Overall QMS responsibility and authority is as follows:

Top Management – Members of Top Management are ultimately responsible for the quality of our company's products and services since they control the systems and processes by which work is accomplished. Top Management is responsible for Business Planning, development and communication of Quality Policy, QMS Planning (including the establishment and deployment of corporate level objectives), and the provision of resources for implementation and maintenance of the QMS. Top Management also conducts QMS internal audits and reviews.

Management – All managers are responsible for developing the Quality Plan and implementation of the policies, procedures and systems described in this manual. All managers are responsible for planning, controlling QMS processes within their area(s) of responsibility. They are also responsible for the establishment and deployment of operational level objectives and the identification of resources needed to implement and improve these processes.

Employees – Employees are responsible for the quality of their work and implementation of the policies and procedures applicable to processes they perform.

Documents, procedures and authorities for QMS implementation and improvement are contained in this manual and other documents referenced throughout this manual and other QMS documents including flow charts, job descriptions, work instructions, etc.

5.5.2 Management Representative

Instructions: Enter the correct title of the individual who is managing the company's ISO program.

Top management has appointed the **Title of a Staff Member** as the company's Management Representative, who, irrespective of other responsibilities, has responsibility and authority for

- a) ensuring that processes needed for the Quality Management System are established, implemented and maintained,
- b) reporting to top management on the performance of the Quality Management System and any need for improvement, and