

# Quality Manual

Prepared to comply with the requirements of ISO 9001:2000 & TS-16949

## NOTE:

Documents titles referenced in this manual that are [blue font and underlined](#) are directly linked to this manual and may be accessed by clicking on the underlined title.

Document titles that appear in *blue italics* are also linked to the manual and may be accessed from a table of document matrices that appears at the end of the manual.

08 July, 2005

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# ISO/TS QUALITY MANAGEMENT SYSTEM

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## 1. SCOPE

- 1.1. The Quality Management System, as defined by this manual, adheres to the general principles outlined by the ISO-9001-2000 & TS-16949 standards and sound commercial manufacturing practices to achieve a complete system of quality management.
- 1.2. The Quality Manual has been implemented as a reference for the departmental procedures, process maps, and work instructions that are associated with the Quality System, to ensure that the organization's goals and the expectation and needs of our customers are met.
- 1.3. The Quality Manual contains links to related documents and a table showing these documents appears at the end of the manual.

## 2. NORMATIVE REFERENCE

The Quality Manual adheres to the requirements of the ISO9001:2000 & TS-16949 Standards. The Quality Manual is applicable to this company's design, development, production, and servicing of the product manufactured and makes no exclusions to the requirements of the applicable standard.

## 3. TERMS AND DEFINITIONS

- 3.1. The following terms and definitions have been established for the quality management system:

**Audit** - A documented investigation conducted by the company or for the company to verify that applicable requirements are being effectively implemented.

**Calibration** - Comparison of two measuring tools or instruments, of which one is a standard with known accuracy.

**COPS** - Customer Oriented Processes

**Management Review** - Monthly report(s) delivered to top management on the performance of the quality management system, key measurable(s), and measurable internal objectives including any need for improvement(s).

**Non-Conformity** - The non-fulfillment of specified requirements.

**Output** - Achieved within the process as a direct result of an input

**Preventive Action** - Action taken to eliminate the causes of a potential nonconformity, defect or other undesirable situation in order to prevent occurrence before it actually occurs. This is done by analysis of records and other relevant sources of information for trends that may adversely affect quality.

**Process Map** - A map (generally in the form of a flowchart) that illustrates the facilities core processes and is developed by gathering data, analyzing that data, adjusting the process based upon results, and then effectively deploying, monitoring and enforcing the new process.

**Verification** - Investigation to confirm that an activity, product, or service conforms to specified plans or requirements.

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# ISO/TS QUALITY MANAGEMENT SYSTEM

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## 4. QUALITY MANAGEMENT SYSTEM

- 4.1. The facility has established, documented, implemented, maintained, and continually improves its quality management system in accordance with the requirements of the ISO 9000:2000 or TS-16949 Standard. Additionally, the facility:
- Has identified the processes needed for the quality management system on the [Process Map Overview](#) and their application throughout the organization
  - Determined the sequence and interaction of these processes
- 4.2. Documentation Requirements
- 4.2.1. The [Quality Policy](#) is established to continually improve the quality of our employees and the products that we design, manufacture, and service to ensure total customer satisfaction. Quality objectives are established, reviewed, and further documented by the Management Review Team in order to meet the goals of the quality policy as directed by the business plan.
- 4.2.2. The Quality Manual includes the scope of the Quality Management System. The Quality Manual contains no exclusions to the ISO 9001:2000 or TS-16949 Standard. A process map that provides a description of the interaction between the processes of the Quality Management System is included in the [Process Map Overview](#).
- 4.2.2.1. The [4.2.3 Control of Documents](#) Procedure ensures that essential documents such as drawings, technical requirements, specifications and Quality System documentation are defined, reviewed, approved prior to issue, updated and re-approved by authorized personnel and relevant versions are

## 5. MANAGEMENT RESPONSIBILITY

- 5.1. Management Commitment is addressed on a monthly and an annual basis. The Management Review Team establishes [Quality Goals and Internal Objectives](#) in line with the Strategic Business Plan in order to meet the
- 5.2. Planning
- 5.2.1. The Quality Management System is designed to ensure that [Quality Goals and Internal Objectives](#) are established at relevant functions and levels within facility through the [5.4.0 Planning Work Instruction](#). The Management Review Team ensures that quality objectives and key measurable(s) are measurable and consistent, and essential activities and resources are in place to satisfy the Quality Policy.
- 5.2.1.1. [Quality Goals and Internal Objectives](#) will be included in the strategic business plan to drive the Quality Policy. Customer expectations and timeframes will be identified.
- 5.2.2. Quality management system planning is outlined in [5.4.0 Planning Work Instruction](#) and the integrity of the QMS is maintained when changes to the system are planned and implemented.
- 5.3. Responsibility, Authority, and Communication
- 5.3.1. The Management Review Team will appoint a Management Representative with the responsibility and
- 5.4. Management Review
- 5.4.1. Management Review of the QMS is conducted by the Management Review Team at planned intervals ([5.6.0 Management Review Work Instruction](#)) to ensure its suitability, adequacy and effectiveness as well as:
- 5.4.1.1. System Performance trends of the [Quality Goals and Internal Objectives](#), key measures, and continuous improvement activities are communicated monthly in the Management Review Meetings and evaluated annually to help determine effectiveness of the QMS.

## 6. RESOURCE MANAGEMENT

- 6.1. The Management Review Team determines resource needs. This ensures that adequate resources are available to maintain the Quality Management System and continually improve its effectiveness.

# ISO/TS QUALITY MANAGEMENT SYSTEM

6.2. Human Resources requirements are met through:

6.2.1. Personnel performing work with potential to affect quality are hired on the basis of appropriate education, training, skills and/or experience. Job descriptions of individual functions define the duties, minimum qualifications and requirements, responsibilities and authorities. Job Descriptions are linked to the [Organizational Chart](#).

6.2.2. The requirements concerning competence, awareness, and training are addressed in the [6.2.2 Competence, Awareness, & Training](#) Procedure. This procedure further outlines the methods, responsibilities, and defines the resources needed to provide, implement and continually improve the processes of the Quality Management System.

6.2.2.1.products if available.

Links to related Documents can be found on the following matrices:

<h2>Procedures Matrix</h2>				
<b>QUALITY MANAGEMENT SYSTEM</b>				
TS Clause Number	Title	Original Issue Date	TS Reference	Facility Reference
4.2.3	<a href="#">Control of Documents</a>		<b>4.0</b>	
4.2.4	Control of Records			
<b>MANAGEMENT RESPONSIBILITY</b>				
TS Clause Number	Title	Original Issue Date	TS Reference	Facility Reference
			<b>5.0</b>	
<b>RESOURCE MANAGEMENT</b>				
TS Clause Number	Title	Original Issue Date	TS Reference	Facility Reference
6.2.2	<a href="#">Competence, Awareness, &amp; Training</a>		<b>6.0</b>	
<b>PRODUCT REALIZATION</b>				
TS Clause Number	Title	Original Issue Date	TS Reference	Facility Reference
			<b>7.0</b>	

# ISO/TS QUALITY MANAGEMENT SYSTEM

MEASUREMENT, ANALYSIS & IMPROVEMENT				
TS Clause Number	Title	Original Issue Date	TS Reference	Facility Reference
8.2.2	<a href="#">Internal Product-Process Audit</a>		<b>8.0</b>	
8.3.0	<a href="#">Control of Nonconforming Product</a>			
8.5.2	<a href="#">Corrective Action</a>			
8.5.3	<a href="#">Preventive Action</a>			

## Work Instruction Matrix

QUALITY MANAGEMENT SYSTEM				
TS Clause Number	Title	Original Issue Date	TS Reference	Facility Reference
			<b>4.0</b>	
MANAGEMENT RESPONSIBILITY				
TS Clause Number	Title	Original Issue Date	TS Reference	Facility Reference
5.4.0	<a href="#">Planning</a>		<b>5.0</b>	
RESOURCE MANAGEMENT				
TS Clause Number	Title	Original Issue Date	TS Reference	Facility Reference
			<b>6.0</b>	

# ISO/TS QUALITY MANAGEMENT SYSTEM

## PRODUCT REALIZATION

TS Clause Number	Title	Original Issue Date	TS Reference	Facility Reference
7.4.3.1	<a href="#">Receiving Inspection</a>		<b>7.0</b>	
7.5.2	<a href="#">Final Audit</a>			

## MEASUREMENT, ANALYSIS & IMPROVEMENT

TS Clause Number	Title	Original Issue Date	TS Reference	Facility Reference
8.2.4.0	<a href="#">In-Process Inspection</a>		<b>8.0</b>	

## Forms Matrix

Form Number	Description	Original Issue Date
	<a href="#">Continuous Improvement Task List</a>	

## Records Matrix

Reference Number	Description	Location	Owner	Retention Time	Disposal Method
	8-D Corrective Action Report				
	Annual Revalidation Records				
	Bill of Lading				
	Customer Invoices				
	Supplier Invoices				
	Canceled Checks				

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# ISO/TS QUALITY MANAGEMENT SYSTEM

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	Management Review Minutes				
	Customer Complaints				
	Employee Training Records				
	Supplier Complaints				

Additional document links:

[External Reference Documents Matrix](#)

[Organizational Chart](#)

[Quality Goals and Internal Objectives](#)

[Process Map](#)

[Quality Policy](#)

Date	Rev	Change Record