

# Quality Requirements for Suppliers

---

CSQ2000 Rev. D

**Revised**

**10/07/2022**



Custom Tube Products, Inc.  
317 Base Leg Drive  
Edgewater, FL 32132

CSQ2000 Rev. D  
Quality Requirements for Suppliers

### APPROVALS

*John Butler*      October 7, 2022

---

John J. Butler III, Quality Manager  
John.butler@customtubeproducts.com  
(386) 426-0670

*David Love*      October 7, 2022

---

David Love, President  
sales@customtubeproducts.com  
(386) 426-0670, Ext. 11



# CONTENTS

<b>1</b>	<b>Purpose and Scope</b> .....	<b>5</b>
1.1	Purpose.....	5
1.2	Scope.....	5
<b>2</b>	<b>General Requirements</b> .....	<b>5</b>
<b>3</b>	<b>Context of the Organization</b> .....	<b>5</b>
3.1	General.....	5
3.2	Quality management system and its processes .....	6
<b>4</b>	<b>Leadership</b> .....	<b>6</b>
4.1	Leadership and commitment.....	6
4.2	Customer Focus.....	6
<b>5</b>	<b>Planning</b> .....	<b>6</b>
5.1	Actions to address risks and opportunities.....	6
5.2	Quality Objectives and planning to meet them .....	6
5.3	Planning of Changes .....	7
<b>6</b>	<b>Support</b> .....	<b>7</b>
6.1	General.....	7
6.2	PEOPLE.....	7
6.3	Infrastructure.....	7
6.4	Monitoring and measuring resources and measurement traceability.....	7
6.5	Organizational knowledge.....	8
6.6	Competence, training and awareness.....	8
6.7	Documented information.....	8
6.7.1	General.....	8
6.7.2	Creating and updating.....	8
6.7.3	Control of documented information.....	8
<b>7</b>	<b>Operations</b> .....	<b>9</b>
7.1	Operational planning and control .....	9
7.2	Requirements for products and services.....	9
7.2.1	Customer Communication.....	9
7.2.2	Determination the requirements for product and services.....	10
7.2.3	Review of the requirements for products and services.....	10



7.2.4	Changes to requirements for products and services .....	10
7.3	Design and development of products and services.....	10
7.3.1	Design and development planning.....	10
7.3.2	DESIGN AND DEVELOPMENT INPUTS.....	11
7.3.3	Design and development controls.....	11
7.3.4	DESIGN AND DEVELOPMENT OUTPUTS .....	11
7.3.5	Design and development changes .....	11
7.4	Control of externally provided processes, products, and services .....	12
7.4.1	General.....	12
7.4.2	Type and extent of control.....	12
7.4.3	Information for external providers.....	12
7.5	Control of production and services provision .....	12
7.5.1	Identification and traceability.....	13
7.5.2	Property belonging to customer or external providers .....	13
7.5.3	Preservation .....	13
7.5.4	Control of changes.....	13
7.6	Release of products and services.....	13
7.7	Control of Nonconforming outputs.....	13
<b>8</b>	<b>Performance Evaluations</b> .....	<b>14</b>
8.1	Monitoring, measurement, analysis, and evaluation.....	14
8.1.1	GENERAL.....	14
8.1.2	Customer Satisfaction.....	14
8.2	INTERNAL AUDIT .....	14
8.3	MANAGEMENT REVIEW .....	15
8.3.2	Management review inputs.....	15
8.3.3	Management review outputs.....	15
<b>9</b>	<b>Improvement</b> .....	<b>16</b>
9.1	General.....	16
9.2	Nonconformity and corrective action.....	16
9.3	Continual improvement.....	16

# **1 PURPOSE AND SCOPE**

## **1.1 PURPOSE**

This document contractually applies when referenced on purchase orders or contracts issued by Custom Tube Products, Inc. (CTP). Deviations to the quality system requirements included herein shall be approved by the CTP Quality Manager. Requests for deviation shall be documented and submitted to CTP Quality.

In the event that the purchase order or contract conflicts with the requirements of this document, the purchase order/contract requirement will supersede this document.

## **1.2 SCOPE**

This document establishes CTP quality system requirements for suppliers. These requirements apply to manufacturers, distributors, and special processors providing parts/services for CTP when this document is specified by inclusion on purchase orders or contracts issued by CTP.

# **2 GENERAL REQUIREMENTS**

Supplier shall guarantee right of access to their facilities and quality related data to regulatory authorities, CTP customers, and CTP. Access by CTP customers shall only be granted with sufficient prior notice to CTP and with CTP's concurrence. This right of access shall extend to include all sub-tier and raw material suppliers.

Supplier shall flow down to sub-tier suppliers all applicable requirements of this document or other purchase order requirements in the purchasing documents.

Unless specified otherwise and where applicable, Supplier shall be in compliance with the latest revision of applicable documents including but not limited to ASTM, SAE and ASME.

# **3 CONTEXT OF THE ORGANIZATION**

## **3.1 GENERAL**

The supplier's organization shall demonstrate that it understands all internal and external influences that may affect its strategic direction and market position and what effect any changes may have on its future. The organization shall determine the interested parties that are relevant to the quality management system and the requirements of these interested parties that are relevant to the quality management system.



### 3.2 QUALITY MANAGEMENT SYSTEM AND ITS PROCESSES

The supplier's organization shall establish, implement and maintain an effective quality management system, including processes needed, preferably one that conforms to ISO 9001:2015 Quality Management Systems - Requirements and continually improve its effectiveness.

## 4 LEADERSHIP

### 4.1 LEADERSHIP AND COMMITMENT

Supplier's top management shall demonstrate leadership and commitment to the supplier's quality management system. They should ensure that the quality policy and objective are compatible with the business's direction and the policy is understood and followed.

### 4.2 CUSTOMER FOCUS

Supplier's top management shall demonstrate leadership and commitment to ensure that customer and applicable statutory and regulatory requirements are determined, understood and met. The need to identify and address any risk to conformity of goods and services provided to customers and to focus on customer satisfaction.

## 5 PLANNING

### 5.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

When planning for the quality management system, the Supplier's top management shall consider external and internal issues and the requirements of these interested parties and determine the risks and opportunities that need to be addressed to:

- a) enhance desirable effects
- b) prevent, or reduce, undesired effects
- c) achieve improvement

### 5.2 QUALITY OBJECTIVES AND PLANNING TO MEET THEM

Supplier's top management shall establish quality objectives at relevant functions and levels within the organization. The quality objectives shall be measurable, consistent with the quality policy, and be relevant to conformity of products and services and to enhancement of customer satisfaction.

Supplier's top management shall ensure that

- a) the planning of the quality management system is carried out to determine and evaluate applicable risks, as well as 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

### 5.3 PLANNING OF CHANGES

When the supplier's organization determines the need for change to the quality management system, they shall be carried out in a planned manner, they shall consider:

- a) the purpose of the change and their potential consequences
- b) the integrity of the quality management system

## 6 SUPPORT

### 6.1 GENERAL

Supplier's organization shall determine and provide resources needed for the implementation, maintenance, and continual improvement of the quality management system.

### 6.2 PEOPLE

Supplier's organization shall determine and provide the personal necessary for the implementation of its quality management system of it processes.

### 6.3 INFRASTRUCTURE

Supplier's organization shall determine, provide, and maintain the work environment and infrastructure necessary for the operation of its processes and to achieve conformity to product requirements.

### 6.4 MONITORING AND MEASURING RESOURCES AND MEASUREMENT TRACEABILITY

Supplier's organization shall determine and provide the resources needed to ensure valid and reliable results of conformity of product and services to the requirements.

Supplier's organization shall ensure that the resources provided:

- a) are suitable for the type of monitoring and measurement activities being conducted
- b) are maintained to ensure their continuing fitness for their purpose
- c) retain appropriate documentation as evidence of fitness for monitoring and measurement resources

When measurement traceability is a requirement or considered by the suppliers top management to be essential, measuring equipment shall be:

- a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be documented.
- b) identified in order to determine their status.
- c) have identification in order to determine its calibration status.
- d) safeguarded from adjustments, damaged or deterioration that would invalidate the calibration status and measurement result.

The supplier's organization shall determine the validity of the previous measuring results when the equipment is found not meeting requirements. The supplier's organization shall take appropriate action as necessary.

## 6.5 ORGANIZATIONAL KNOWLEDGE

The supplier's organization shall take steps to identify the internal and external knowledge necessary to ensure the continued product conformity. This knowledge shall be maintained and available as necessary.

## 6.6 COMPETENCE, TRAINING AND AWARENESS

The supplier's organization shall:

- a) Have a process for assessing existing staff competencies against changing business needs and trends
- b) Ensure that employees are aware of the implications of not conforming to the quality management system
- c) Communicate with internal and external parties relevant to the quality management system

## 6.7 DOCUMENTED INFORMATION

### 6.7.1 GENERAL

The supplier's quality management system shall include:

- a) documented information required by an International Standard
- b) documented information determined by the organization as being necessary for the effectiveness of the quality management system

### 6.7.2 CREATING AND UPDATING

When creating and updating documented information the supplier's organization shall ensure:

- a) identification and description
- b) format and media
- c) review and approvable for adequacy

### 6.7.3 CONTROL OF DOCUMENTED INFORMATION

Documented information required by the supplier's quality management system shall be controlled to ensure:

- a) it is available and suited for use, when and where needed
- b) it is adequately protected

For control of documented information, the supplier's organization shall address the following, as applicable:



- a) distribution, access, retrieval, and use
- b) storage and preservation
- c) control of changes
- d) retention and disposition

Supplier's documented information retained as evidence of conformity shall be protected from unintended alterations. Corrections to quality records must be recorded, dated, and signed in ink or other permanent marking method with the original data being legible and retrievable after the change.

All quality records and documentation, both hard copy and electronic, related to CTP orders shall be maintained on file for a minimum of ten years or the expected life of the product, whichever is greater.

## **7 OPERATIONS**

### **7.1 OPERATIONAL PLANNING AND CONTROL**

Supplier's organization shall plan, implement, and control the processes needed to meet the requirements for product and services.

In planning of the product and service, the supplier's organization shall determine the following:

- a) determining the requirements for the product and services
- b) establishing criteria for processes and the acceptance of products and services
- c) determining the resources needed to achieve conformity
- d) implementing control of the processes
- e) determining, maintaining, and retaining documented information as necessary

The output of this planning shall be suitable for the supplier's organization's operations.

The supplier's organization shall ensure that outsourced processes are controlled.

### **7.2 REQUIREMENTS FOR PRODUCTS AND SERVICES**

#### **7.2.1 CUSTOMER COMMUNICATION**

Supplier's organization communication with customers shall include:

- a) providing information relating to the product and services,
- b) handling enquiries, contracts, or order, including changes,
- c) obtaining customer feedback relating to products and services, including customer complaints
- d) handling and controlling customer property
- e) establishing specific requirements for contingency action as needed

## 7.2.2 DETERMINATION THE REQUIREMENTS FOR PRODUCT AND SERVICES

Supplier's organization shall determine:

- a) The requirements for the product and services are defined, including
- b) any applicable statutory and regulatory requirements, and
- c) those considered necessary by the organization.

## 7.2.3 REVIEW OF THE REQUIREMENTS FOR PRODUCTS AND SERVICES

Supplier's organization shall review the requirements related to the product. This review shall be conducted prior to the supplier's organization's commitment to supply a product and service to the customer, to include:

- a) requirements specified by the customer, including requirements for delivery
- b) statutory and regulatory requirements applicable to the product and services
- c) supplier's organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the supplier's organization before acceptance.

Where product requirements are changed, the supplier's organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

## 7.2.4 CHANGES TO REQUIREMENTS FOR PRODUCTS AND SERVICES

Supplier's organization shall ensure that all relevant documented information relating to change in the product or service requirements is amended and relevant personal are made aware of the changed requirements.

## 7.3 DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES

### 7.3.1 DESIGN AND DEVELOPMENT PLANNING

Supplier's organization shall establish, implement, and maintain a design and development process of product and services.

During the design and development planning, the supplier's organization shall consider:

- a) the design and development activities,
- b) the review, verification and validation that are appropriate to each design and development activity, and
- c) the responsibilities and authorities for design and development.
- d) the internal and external resource needs for the design and development of product and services
- e) documented information needs to demonstrate that the design and development requirements have been met.

### 7.3.2 DESIGN AND DEVELOPMENT INPUTS

Inputs relating to product and service requirements shall be determined and retain documented information.

These inputs shall include:

- a) functional and performance requirements,
- b) applicable statutory and regulatory requirements,
- c) where applicable, information derived from previous similar designs, and
- d) other requirements essential for design and development.

The inputs shall be adequate for design and development purposes, complete and unambiguous, with conflicts resolved.

### 7.3.3 DESIGN AND DEVELOPMENT CONTROLS

The supplier's organization shall apply controls to the design and development process to ensure:

- a) the results to be achieved and defined.
- b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements, and
- c) Verification activities are conducted to ensure that the design and development outputs meet the input requirements
- d) Any actions taken on problems determined during reviews or verification and validation activities are documented

### 7.3.4 DESIGN AND DEVELOPMENT OUTPUTS

Design and development outputs shall:

- a) meet the input requirements for design and development,
- b) are suitable for the processes for the provisions of the product and services,
- c) contain or reference product acceptance criteria, and
- d) specify the characteristics of the product that are essential for its safe and proper use.

Documented information shall be retained for design and development outputs.

### 7.3.5 DESIGN AND DEVELOPMENT CHANGES

Design and development changes shall be identified, and records maintained. The changes shall be reviewed, verified, and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on product and services already delivered.



## 7.4 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS, AND SERVICES

### 7.4.1 GENERAL

Supplier's organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established.

Supplier's organization shall ensure that documented information records; not only criteria by which suppliers were selected, but also the results of the selection activities, and the results from monitoring of their performance.

### 7.4.2 TYPE AND EXTENT OF CONTROL

Supplier's organization shall ensure that the supplied product or service meets the specified requirements by implementing a process of inspection to ensure that purchased product conform.

Supplier's organization shall:

- a) ensure that externally provided process remain with in control of its quality management system
- b) define the controls that it intends to apply.
- c) determine the verification or other activities necessary to ensure that the externally provided processes, products and services meet requirements.

### 7.4.3 INFORMATION FOR EXTERNAL PROVIDERS

Supplier's organization shall establish methods for communicating their intentions in terms of controlling and monitoring external providers performance to external providers.

- a) the approvable of product and services,
- b) methods, processes, and equipment
- c) release of products and services

## 7.5 CONTROL OF PRODUCTION AND SERVICES PROVISION

Supplier's organization shall control the conditions by which products or services are provided.

Controlled conditions shall include, as applicable,

- a) the availability of documented information that describes the characteristics of the product, services provided, or activities performed
- b) the availability and use of suitable monitoring and measuring resources,
- c) the implementation of monitoring and measurement, at appropriate stages and acceptance criteria for products and services have been met,
- d) the implementation of release, delivery, and post-delivery activities.

### 7.5.1 IDENTIFICATION AND TRACEABILITY

Where traceability is a requirement the supplier's organization must control and record the unique identification of the product.

Supplier's organization shall identify the product status with respect to monitoring and measurement requirements throughout production and service provisions.

### 7.5.2 PROPERTY BELONGING TO CUSTOMER OR EXTERNAL PROVIDERS

Supplier's organization shall exercise care with property belonging to customers or external providers while under organization's control or being used by the supplier.

Supplier's organization shall identify, verify, protect, and safeguard customer or external providers property provided for use or incorporation into the products and services. If any customer property is lost, damaged, or otherwise found to be unsuitable for use, the supplier's organizations shall report this to the customer or external provider and retain documented information.

### 7.5.3 PRESERVATION

Supplier's organization is expected to take adequate measures to protect / preserve the product during internal processing and delivery to the customer. As applicable, preservation shall include identification, handling, packaging, storage, and protection.

### 7.5.4 CONTROL OF CHANGES

The supplier's organization shall review and control changes as necessary to ensure continuing conformity with requirements. Changes should be documented, and information retained about the changes, including who authorized the change and the action arising from the change.

## 7.6 RELEASE OF PRODUCTS AND SERVICES

Supplier's organization shall show evidence that a process (method, techniques, format, etc.) is in place to monitor and measure the characteristics of products to verify that requirements are being met. The documented information shall include traceability to the person authorizing the release and evidence of conformity with acceptance criteria.

## 7.7 CONTROL OF NONCONFORMING OUTPUTS

Supplier's organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery and shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services.

Where applicable, the supplier's organization shall deal with nonconforming outputs by one or more of the following ways:

- a) correction

- b) segregation, containment, return or suspension of provision of products and services
- c) informing the customer
- d) obtaining authorization for acceptance under concession

The supplier's organization shall retain documented information:

- a) describing the nonconformity
- b) describing the actions taken
- c) describing any concessions obtained
- d) identifies the authority for deciding the actions in respect to the nonconformity

## **8 PERFORMANCE EVALUATIONS**

### **8.1 MONITORING, MEASUREMENT, ANALYSIS, AND EVALUATION**

#### **8.1.1 GENERAL**

Supplier's organization shall determine:

- a) what needs to be monitored and measured.
- b) the methods for monitoring, measuring, analysis, and evaluation needed to ensure results
- c) when the monitoring and measurement shall be performed

The supplier's organization shall retain appropriate documented information as evidence.

#### **8.1.2 CUSTOMER SATISFACTION**

The supplier's organization shall monitor the customers perceptions to which their expectations have been met. The organization shall determine the methods for obtaining, monitoring, and reviewing this information.

#### **8.1.3 ANALYSIS AND EVALUATION**

Supplier's organization shall develop a process (method, techniques, format, etc.) to identify, collect and analyze and evaluate data and information from both internal and external sources.

The analysis of data shall provide information relating to

- a) customer satisfaction,
- b) conformity to product and services,
- c) the effectiveness of actions taken to address risks and opportunities
- d) the need for improvements to the quality management system

### **8.2 INTERNAL AUDIT**

Supplier's organization shall conduct internal audits at planned intervals to determine whether the quality management system

- a) conforms to the organizations own requirements for its quality management system and to the requirements of the International Standard
- b) is effectively implemented and maintained.

The supplier's organization shall plan, implement, and maintain an audit program, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. The organization shall retain documented information as evidence of the implementation of the audit program and the audit results.

### 8.3 MANAGEMENT REVIEW

#### 8.3.1 GENERAL

Supplier's top management shall periodically review the QMS to ensure its continuing suitability and adequacy. The organization's management review process shall include discussion of internal and external changes and its potential effect on the direction of the organization.

#### 8.3.2 MANAGEMENT REVIEW INPUTS

The management review shall be planned and carried out taking into consideration:

- a) status and actions from previous management reviews,
- b) changes in external and internal issues that are relevant to quality management system
- c) information on the performance and effectiveness of the quality management system and trends
- d) the effectiveness of actions taken to address risks and opportunities
- e) adequacy of resources
- f) opportunities for improvement

#### 8.3.3 MANAGEMENT REVIEW OUTPUTS

The outputs of the management review shall include decisions and actions related to:

- a) opportunities for improvement
- b) and need for changes to the quality managements system
- c) resources needed

The supplier's organization shall retain documented information as evidence of the results of management review.

## **9 IMPROVEMENT**

### **9.1 GENERAL**

Supplier's organization shall consider improvements with respect to its processes, products, and services, and the performance of the quality management system overall and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

### **9.2 NONCONFORMITY AND CORRECTIVE ACTION**

When a nonconformity occurs the supplier's organization shall take action to control and correct it and deal with the consequences. Evaluate the need for action to eliminate the cause of the nonconformity to ensure it does not recur or occur elsewhere. The organization shall implement any action needed, review the effectiveness of any corrective action taken, and make changes to the quality management system if necessary.

The supplier's organization shall retain documented information as evidence of the nonconformity actions taken and results of any corrective actions.

### **9.3 CONTINUAL IMPROVEMENT**

Supplier's organization shall continually improve the suitability and effectiveness of the quality management system. The organization shall consider results of evaluations and outputs from management review to determine if there are needs or opportunities that shall be addressed as part of continual improvement.



