Custom Tube Products, Inc.
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Quality Requirements for Suppliers

CSQ2000 Rev. C

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APPROVALS

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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 QUALITY MANAGEMENT SYSTEM

3.1 GENERAL REQUIREMENTS

The supplier shall establish, document, implement and maintain a quality management system and continually improve its effectiveness.

3.2 DOCUMENTATION REQUIREMENTS

3.2.1 GENERAL

The supplier's quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,
b) a quality manual,

c) documented procedures and records required by this document, and
d) documents, including records, determined by the supplier to be necessary to ensure the effective planning, operation and control of supplier's processes.

3.2.2 Quality Manual

The supplier shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of, and justification for, any exclusions,
b) the documented procedures established for the quality management system, or reference to them, and
c) a description of the interaction between the processes of the quality management system.

3.2.3 Control of Documents

Documents required by supplier's quality management system shall be controlled according to the requirements given in 3.2.4.

Supplier shall establish a documented procedure to define 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 determined by the supplier to be 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.

3.2.4 Control of Records

Records established to provide evidence of conformity to requirements and of the effective operation of the supplier's quality management system shall be controlled.

The supplier shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Supplier's records shall remain legible, readily identifiable and retrievable. 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.

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.

4 Management Responsibility

4.1 Management Commitment

Supplier's top management shall provide evidence of its commitment to the development and implementation of the supplier's quality management system and continually improving its effectiveness by

a) communicating to the supplier's organization the importance of meeting customer as well as statutory and regulatory requirements,
b) establishing the quality policy,
c) ensuring that quality objectives are established,
d) conducting management reviews, and
e) ensuring the availability of resources.

4.2 Customer Focus

Supplier's top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

4.3 Planning

4.3.1 Quality Objective

Supplier's top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

4.3.2 Quality Management System Planning

Supplier's top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 1.1, 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 RESOURCE MANAGEMENT

5.1 Human Resources

5.1.1 General

Supplier's personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

5.1.2 Competence, Training and Awareness

Supplier's organization shall

a) determine the necessary competence for personnel performing work affecting conformity to product requirements,

b) where applicable, provide training or take other actions to achieve the necessary competence,
c) evaluate the effectiveness of the actions taken,
d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
e) maintain appropriate records of education, training, skills and experience.

5.2 Work Environment

Supplier's organization shall determine and manage the work environment needed to achieve conformity to product requirements.

6 Product Realization

6.1 Planning of Product Realization

Supplier's organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the products;
b) the need to establish processes and documents, and to provide resources specific to the product;
c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
d) records needed to provide evidence that the realization processes and resulting product meet requirements.

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

6.2 Customer-related Processes

6.2.1 Determination of Requirements Related to the Product

Supplier's organization shall determine

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
b) requirements not stated by the customer but necessary for specified or intended use, where known,
c) statutory and regulatory requirements applicable to the product, and
d) any additional requirements considered necessary by the organization.

6.2.2 Review of Requirements Related to the Product

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 to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) product requirements are defined,
b) contract or order requirements differing from those previously expressed are resolved, and
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.

6.2.3 Customer Communication

Supplier's organization shall determine and implement effective arrangements for communicating with customers in relation to

a) product information,
b) enquiries, contracts or order handling, including amendments, and
c) customer feedback, including customer complaints.

6.3 Design and Development

6.3.1 Design and Development Planning

Supplier's organization shall plan and control the design and development of product.

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

a) the design and development stages,
b) the review, verification and validation that are appropriate to each design and development stage, and
c) the responsibilities and authorities for design and development.

6.3.2 Design and Development Inputs

Inputs relating to product requirements shall be determined and records maintained. 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 reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

6.3.3 Design and Development Output

The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,
b) provide appropriate information for purchasing, production and service provision,
c) contain or reference product acceptance criteria, and
d) specify the characteristics of the product that are essential for its safe and proper use.

6.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements

a) to evaluate the ability of the results of design and development to meet requirements, and
b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained.

6.3.5 Design and Development Verification

Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained.

6.3.6 Control of 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 constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained.

6.4 Purchasing

6.4.1 Purchasing Process

Supplier's organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

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. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

6.4.2 Purchasing Information

Supplier's purchasing information shall describe the product to be purchased, including, where appropriate,

a) requirements for approval of product, procedures, processes and equipment,
b) requirements for qualification of personnel, and
c) quality management system requirements.

Supplier's organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

6.4.3 Verification of Purchased Product

Supplier's organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where supplier's organization or its customer intends to perform verification at the supplier's premises, CTP's supplier's organization shall state the intended verification arrangements and method of product release in the purchasing information.

6.5 Production and Service Provision

6.5.1 Control of Production and Service Provision

Supplier's organization shall plan and carry out production and service provision under controlled conditions.

Controlled conditions shall include, as applicable,

a) the availability of information that describes the characteristics of the product,
b) the availability of work instructions, as necessary,
c) the use of suitable equipment,
d) the availability and use of monitoring and measuring equipment,
e) the implementation of monitoring and measurement, and
f) the implementation of product release, delivery and post-delivery activities.

6.5.2 Validation of Processes for Production and Service Provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable,

a) defined criteria for review and approval of the processes,
b) approval of equipment and qualification of personnel,
c) use of specific methods and procedures,
d) requirements for records, and
e) revalidation.

6.5.3 Identification and Traceability

Where appropriate, supplier's organization shall identify the product by suitable means throughout product realization.

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

Where traceability is a requirement, supplier's organization shall control the unique identification of the product and maintain records.

6.5.4 Customer Property

Supplier's organization shall exercise care with customer property while it is under supplier's organization's control or being used by the supplier. Supplier's organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the supplier shall report this to the customer and maintain records.

6.5.5 Preservation of Product

Supplier's organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

6.6 Control of Monitoring and Measuring Equipment

Supplier's organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

Supplier's organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

a) be 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 recorded;
b) be adjusted or re-adjusted as necessary;
c) have identification in order to determine its calibration status;
d) be safeguarded from adjustments that would invalidate the measurement result;
e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected.

Records of the results of calibration and verification shall be maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

7 MEASUREMENT, ANALYSIS AND IMPROVEMENT

7.1 GENERAL

Supplier's organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity to product requirements,
b) to ensure conformity of the quality management system, and
c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

7.2 MONITORING AND MEASUREMENT

7.2.1 CUSTOMER SATISFACTION

As one of the measurements of the performance of the quality management system, the supplier's organization shall monitor information relating to customer perception as to whether the supplier's organization has met customer requirements. The methods for obtaining and using this information shall be determined.

7.2.2 INTERNAL AUDIT

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

a) conforms to the planned arrangements, to the requirements of this International Standard and to the quality management system requirements established by the organization, and
b) is effectively implemented and maintained.

An audit program shall be planned, 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.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results shall be maintained.

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

7.2.3 Monitoring and Measurement of Processes

Supplier's organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

7.2.4 Monitoring and Measurement of Product

Supplier's organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorizing release of product for delivery to the customer.

The release of product and delivery of service to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

7.3 Control of Nonconforming Product

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. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

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

a) by taking action to eliminate the detected nonconformity;
b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
c) by taking action to preclude its original intended use or application;
d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.

7.4 Analysis of Data

Supplier's organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

a) customer satisfaction,
b) conformity to product requirements,
c) characteristics and trends of processes and products, including opportunities for preventive action, and
d) suppliers.

7.5 Improvement

7.5.1 Continual Improvement

Supplier's organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

7.5.2 Corrective Action

Supplier's organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

a) reviewing nonconformities (including customer complaints),

b) determining the causes of nonconformities,
c) evaluating the need for action to ensure that nonconformities do not recur,
d) determining and implementing action needed,
e) records of the results of action taken, and
f) reviewing the effectiveness of the corrective action taken.

7.5.3 Preventive Action

Supplier's organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) determining and implementing action needed,
d) records of results of action taken, and
e) reviewing the effectiveness of the preventive action taken.

CHANGE HISTORY		
REVISION	**DESCRIPTION**	**DATE**
BASIC	Initial release	01/01/2004
A	Rewritten based on ISO 9001 quality requirements	04/11/2012
B	Updated section 3.2.4, Control of Records, to include flow down requirement concerning record retention	01/24/2014
C	Added requirement to 2 General Requirements, Supplier shall be in compliance with the latest revision of applicable documents	09/14/2017