CUSTOM TUBE PRODUCTS, INC.

CTPQ2000

Quality Manual

Revision G

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1. Introduction

Custom Tube Products, Inc. (CTP) is a tube fabricating company located in Edgewater, Florida specializing in small and medium diameter tube bending, tube end forming, and complete tube assemblies. CTP produces products for aviation, medical, industrial, and commercial customers. CTP specializes in medium-to-high volume production, but also offer low-volume and prototype services. CTP produces products ranging from simple bent tubes to complex assemblies.

The activities CTP performs include:

- Machining
- Bending
- Forming
- Metal fabrication
- Assembly
- Welding /brazing
- Inspection & test

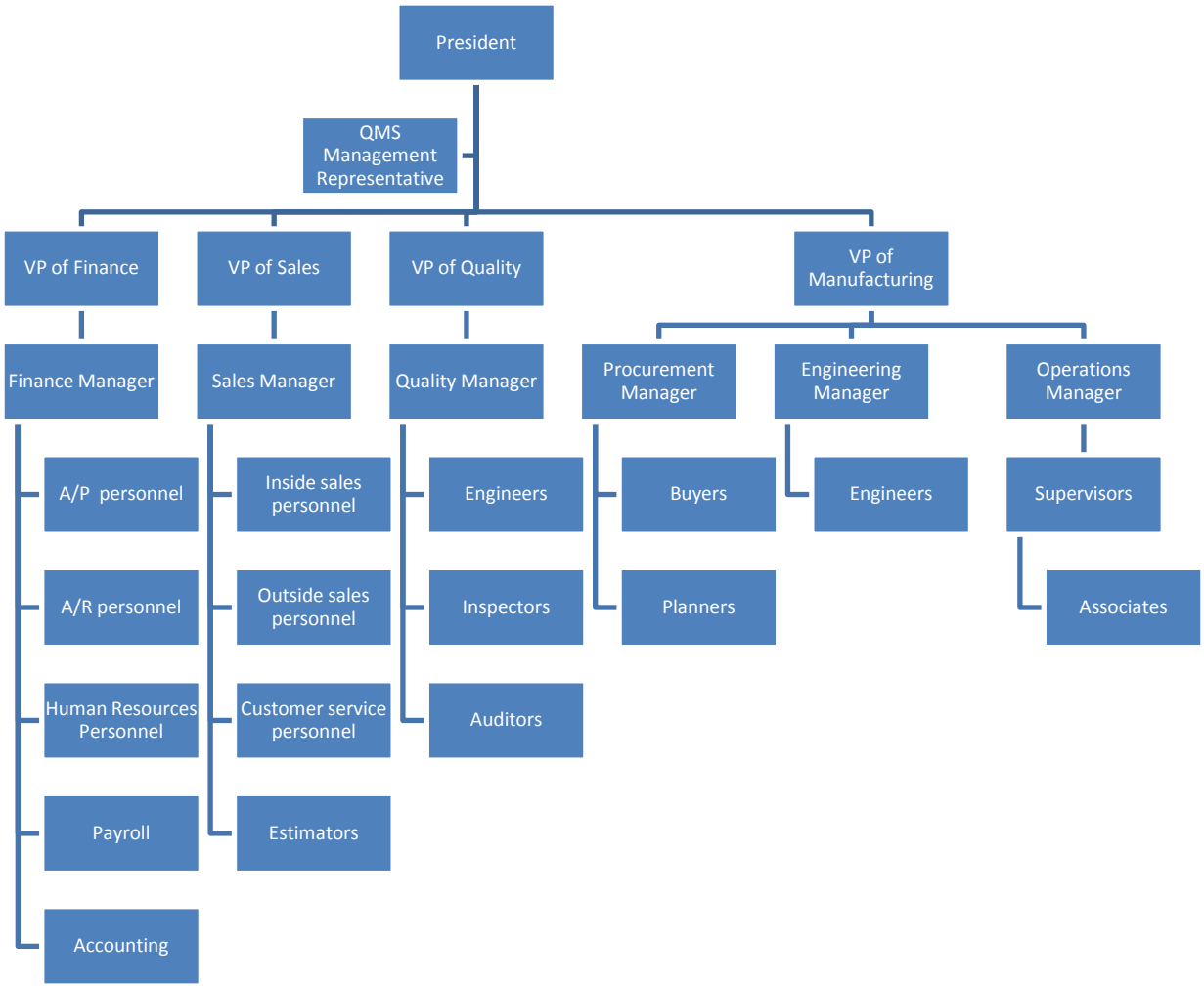

Figure 1. Custom Tube Products Organizational Chart

2. General

The adoption of a quality management system is a strategic decision of an organization. The design and implementation of CTP's quality management system is influenced by

a) its organizational environment, changes in that environment, and the risks associated with that environment,
b) its varying needs,
c) its particular objectives,
d) the products it provides,
e) the processes it employs,
f) its size and organizational structure

3. Terms and Definitions

3.1 Risk

An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

3.2 Special Requirements

Those requirements identified by the customer, or determined by CTP, which have high risks to being achieved, thus requiring their inclusion in the risk management process. Factors used in the determination of special requirements include product or process complexity, past experience and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by CTP to be at the limit of its technical or process capabilities.

3.3 Critical Items

Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

3.4 Key Characteristic

An attribute or feature whose variation has significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation.

4. Quality Management System

4.1 General Requirements

CTP has an established, documented, implemented, and maintained quality management system and works to continually improve its effectiveness.

CTP's quality management system addresses customer and applicable statutory and regulatory quality management system requirements.

CTP

a) determines the processes needed for the quality management system and their application throughout the organization,
b) determines the sequence and interaction of these processes,
c) determines 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 analyses these processes, and
f) implements actions necessary to achieve planned results and continual improvement of these processes.

CTP ensures control over outsourced processes affecting product conformity to requirements. The type and extent of control applied to these outsourced processes is defined within the quality management system.

4.2 Documentation Requirements

4.2.1 General

CTP's quality management system documentation includes

a) documented statements of a quality policy and quality objectives,
b) a quality manual,
c) documented procedures and records required by ISO9001 and AS9100, and
d) documents, including records, determined by CTP to be necessary to ensure the effective planning, operation and control of its processes.

CTP ensures that its personnel have access to, and are aware of, relevant quality management system documentation and changes.

4.2.2 Quality Manual

CTP has established and actively maintains 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.

Reference CTPQ2000, *Quality Manual*

4.2.3 Control of Documents

CTP controls the documents required by the quality management system. CTP has established 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 determined CTP 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.

Reference Standard Operating Procedure (SOP) CTP9423, *Control of Documents*

4.2.4 Control of Records

CTP controls the records established to provide evidence of conformity to requirements and of the effective operation of the quality management system.

CTP has established a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

The documented procedure defines the method for controlling records that are created by and/or retained by suppliers.

CTP ensures records remain legible, readily identifiable and retrievable.

Reference SOP CTP9424, *Control of Records*

5. Management Responsibility

5.1 Management Commitment

Top management is committed to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the 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.

5.2 Customer Focus

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

Top management ensures that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not, or will not be, achieved.

5.3 Quality Policy

Top management ensures that the quality policy

a) is appropriate to the purpose of the organization,
b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
c) provides a framework for establishing and reviewing quality objectives,
d) is communicated and understood within the organization, and
e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality Objectives

Top management ensures that quality objectives, including those needed to meet requirements for product (see 7.1.a), are established at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy.

5.4.2 Quality Management System Planning

Top management ensures that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, 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.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Top management ensures that responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management Representative

Top management has appointed the Quality Manager who, irrespective of other responsibilities, has responsibility and authority that includes

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,
c) ensuring the promotion of awareness of customer requirements throughout the organization, and

d) the organizational freedom and unrestricted access to top management to resolve quality management issues.

5.5.3 Internal Communication

Top management ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management Review

5.6.1 General

Top management reviews the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews are maintained (see 4.2.4).

Reference SOP CTP9560, *Management Review*

5.6.2 Review Input

The input to management review includes information on

a) results of audits,
b) customer feedback,
c) process performance and product conformity,
d) status of preventive and corrective actions,
e) follow-up actions from previous management reviews,
f) changes that could affect the quality management system, and
g) recommendations for improvement.

5.6.3 Review Output

The output from the management review includes any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes,
b) improvement of product related to customer requirements, and
c) resource needs.

6. Resource Management

6.1 Provision of Resources

CTP determines and provides the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and
b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human Resources

6.2.1 General

Personnel performing work affecting conformity to product requirements are competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, Training and Awareness

CTP

a) determines the necessary competence for personnel performing work affecting conformity to product requirements,
b) where applicable, provides training or takes other actions to achieve the necessary competence,
c) evaluates the effectiveness of the actions taken,
d) ensures 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) maintains appropriate records of education, training, skills and experience (see 4.2.4).

Reference SOP CTP9622, *Competence, Training and Awareness*

6.3 Infrastructure

CTP determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable,

a) buildings, workspace and associated utilities,
b) process equipment (both hardware and software), and
c) supporting services (such as transport, communication or information systems).

6.4 Work Environment

CTP determines and manages the work environment needed to achieve conformity to product requirements.

7. Product Realization

7.1 Planning of Product Realization

CTP plans and develops the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, CTP determines the following, as appropriate:

a) quality objectives and requirements for the product;
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 (see 4.2.4);
e) configuration management appropriate to the product;
f) resources to support the use and maintenance of the product.

The output of this planning is in a form suitable for CTP's method of operations.

Reference SOP CTP9710, *Planning of Product Realization*

7.1.1 Project Management

As appropriate to the organization and the product, CTP plans and manages product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints.

7.1.2 Risk Management

CTP establishes, implements and maintains a process for managing risk to the achievement of applicable requirements, that includes as appropriate to the organization and the product

a) assignment of responsibilities for risk management,
b) definition of risk criteria (e.g., likelihood, consequences, risk acceptance),
c) identification, assessment and communication of risks throughout product realization,
d) identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and
e) acceptance of risks remaining after implementation of mitigating actions.

7.1.3 Configuration Management

CTP establishes, implements and maintains a configuration management process that includes, as appropriate to the product

a) configuration management planning,
b) configuration identification,
c) change control,
d) configuration status accounting, and
e) configuration audit.

7.1.4 Control of Work Transfers

CTP establishes, implements and maintains a process to plan and control the temporary or permanent transfer of work (e.g., from one organization facility to another, from the organization to a supplier, from one supplier to another supplier) and to verify the conformity of the work to requirements.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

CTP determines

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

7.2.2 Review of Requirements Related to the Product

CTP reviews the requirements related to the product. This review is conducted prior to CTP'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 ensures that

a) product requirements are defined,
b) contract or order requirements differing from those previously expressed are resolved,
c) CTP has the ability to meet the defined requirements,
d) Special requirements of the product are determined, and
e) Risks (e.g., new technology, short delivery time frame) have been identified (see 7.1.2).

Records of the results of the review and actions arising from the review are maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements are confirmed by CTP before acceptance.

Where product requirements are changed, CTP ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

Reference SOP CTP9722, *Review of Requirements Related to the Product*

7.2.3 Customer Communication

CTP determines and implements 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.

7.3 Design and Development

CTP is a contract manufacturer and does not design and develop the products we sell. As such, CTP takes exception to section 7.3, Design and Development.

7.4 Purchasing

7.4.1 Purchasing Process

CTP ensures that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product are dependent upon the effect of the purchased product on subsequent product realization or the final product.

CTP is responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer.

CTP evaluates and selects suppliers based on their ability to supply product in accordance with CTP's requirements. Criteria for selection, evaluation and re-evaluation have been established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained (see 4.2.4).

CTP

a) maintains a register of its suppliers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family),
b) periodically reviews supplier performance; the results of these reviews are used as a basis for establishing the level of controls to be implemented,
c) defines the necessary actions to take when dealing with suppliers that do not meet requirements,
d) ensures where required that both CTP and all suppliers use customer-approved special process sources,
e) defines the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on the supplier's approval status, and
f) determines and manages the risk when selecting and using suppliers (see 7.1.2).

Reference SOP CTP9741, *Purchasing Process*

7.4.2 Purchasing Information

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

a) requirements for approval of product, procedures, processes and equipment,
b) requirements for qualification of personnel,
c) quality management system requirements,
d) the identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data,
e) requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by CTP, and as applicable critical items including key characteristics,
f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing,

g) requirements regarding the need for the supplier to
    a. notify CTP of nonconforming product,
    b. obtain CTP approval for nonconforming product disposition,
    c. notify CTP of changes in product and/or process, changes of suppliers, changes of manufacturing facility location and, where required, obtain CTP approval, and
    d. flow down to the supply chain the applicable requirements including customer requirements,
h) records retention requirements, and
i) right of access by CTP, its customer and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records.

CTP ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of Purchased Product

CTP establishes and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where purchased product is released for production use pending completion of all required verification activities, it is identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Where CTP delegates verification activities to the supplier, the requirements for delegation are defined and a register of delegations maintained.

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

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

CTP plans and carries out production and service provision under controlled conditions. Controlled conditions 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,
f) the implementation of product release, delivery and post-delivery activities,
g) accountability for all product during production (e.g., parts quantities, split orders, nonconforming product),
h) evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized,

i) provision for the prevention, detection and removal of foreign objects,
j) monitoring and control of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements, and
k) criteria for workmanship, specified in the clearest practical way (e.g., written standards, representative samples, illustrations).

Planning considers, as appropriate

a) establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified,
b) designing, manufacturing and using tooling to measure variable data,
c) identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization, and
d) special processes (see 7.5.2).

7.5.1.1 Production Process Verification

CTP uses a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This process is repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

7.5.1.2 Control of Production Process Changes

Personnel authorized to approve changes to production processes are identified.

CTP controls and documents changes affecting processes, production equipment, tools and software programs.

The results of changes to production processes are assessed to confirm that the desired effect has been achieved without adverse effects to product conformity.

7.5.1.3 Control of Production Equipment, Tools and Software Programs

Production equipment, tools and software programs used to automate and control/monitor product realization processes, are validated prior to release for production and are maintained.

Storage requirements, including periodic preservation/condition checks, are defined for production equipment and tooling in storage.

7.5.1.4 Post-Delivery Support

Post-delivery support provides as applicable for the

a) collection and analysis of in-service data,
b) actions to be taken, including investigation and reporting, when problems are detected after delivery,
c) control and updating of technical documentation,
d) approval, control and use of repair schemes, and

e) controls required for off-site work (e.g., CTP's work undertaken at the customer's facilities).

7.5.2 Validation of Processes for Production and Service Provision

CTP validates 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 demonstrates the ability of these processes to achieve planned results.

CTP establishes 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 (see 4.2.4), and
e) revalidation.

Reference SOP CTP9752, *Validation of Processes for Production and Service Provision*

7.5.3 Identification and Traceability

Where appropriate, CTP identifies the product by suitable means throughout product realization.

CTP maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

CTP identifies the product status with respect to monitoring and measurement requirements throughout product realization.

When acceptance authority media are used (e.g. stamps, electronic signatures, passwords), CTP establishes appropriate controls for the media.

Where traceability is a requirement, CTP controls the unique identification of the product and maintain records (see 4.2.4).

Reference SOP CTP9753, *Identification and Traceability*

7.5.4 Customer Property

CTP exercises care with customer property while it is under CTP's control or being used by CTP. CTP identifies, verifies, protects and safeguards 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, CTP reports this to the customer and maintains records (see 4.2.4).

Reference SOP CTP9754, *Customer Property*

7.5.5 Preservation of Product

CTP preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

Preservation of product also includes, where applicable in accordance with product specifications and applicable statutory and regulatory requirements, provisions for

a) cleaning,
b) prevention, detection and removal of foreign objects,
c) special handling for sensitive products,
d) marking and labeling including safety warnings,
e) shelf life control and stock rotation, and
f) special handling for hazardous materials.

7.6 Control of Monitoring and Measuring Equipment

CTP determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

CTP maintains a register of the monitoring and measuring equipment and defines the process employed for their calibration/verification including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

CTP establishes 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.

CTP ensures that environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out.

Where necessary to ensure valid results, measuring equipment is

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 is recorded (see 4.2.4);
b) adjusted or re-adjusted as necessary;
c) identified in order to determine its calibration status;
d) safeguarded from adjustments that would invalidate the measurement result;
e) protected from damage and deterioration during handling, maintenance and storage.

CTP establishes implements and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification.

In addition, CTP assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. CTP takes appropriate action on the equipment and any product affected.

Records of the results of calibration and verification are maintained (see 4.2.4).

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

Reference SOP CTP9760, *Control of Monitoring and Measuring Equipment*

8. Measurement, Analysis and Improvement

8.1 General

CTP plans and implements 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 includes determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

AS one of the measurements of the performance of the quality management system, CTP monitors information relating to customer perception as to whether CTP has met customer requirements. The methods for obtaining and using this information are determined.

Information to be monitored and used for the evaluation of customer satisfaction includes, but is not limited to, product conformity, on-time delivery performance, customer complaints and corrective action requests. CTP develops and implements plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

8.2.2 Internal Audit

CTP conducts internal audits at planned intervals to determine whether the quality management system

a) conforms to the planned arrangements (see 7.1), to the requirements of this quality manual and to the quality management system requirements established by CTP, and
b) is effectively implemented and maintained.

An audit program is 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 are defined. The selection of auditors and conduct of audits are performed to ensure objectivity and impartiality of the audit process. Auditors do not audit their own work.

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

Records of the audits and their results are maintained (see 4.2.4).

The management responsible for the area being audited ensures that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results (see 8.5.2).

Reference SOP CTP9822, *Internal Audit*

8.2.3 Monitoring and Measurement of Processes

CTP applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action are taken, as appropriate.

In the event of process nonconformity, CTP

a) takes appropriate action to correct the nonconforming process,
b) evaluates whether the process nonconformity has resulted in product nonconformity,
c) determines if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and
d) identifies and controls any nonconforming product (see 8.3).

8.2.4 Monitoring and Measurement of Product

CTP monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria are maintained.

Measurement requirements for product acceptance are documented and include

a) criteria for acceptance and/or rejection,
b) where in the sequence measurement and testing operations are to be performed,
c) required records of the measurement results (at a minimum, indications of acceptance or rejection), and
d) any specific measurement instruments required and any specific instructions associated with their use.

When critical items, including key characteristics, have been identified CTP ensures they are controlled and monitored in accordance with the established processes.

When CTP uses sampling inspection as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).

Where product is released for production use pending completion of all required measurement and monitoring activities, it is identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Records indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

Where required to demonstrate product qualification, CTP ensures that records provide evidence that the product meets the defined requirements.

The release of product and delivery of service to the customer does not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

CTP ensures that all documents required to accompany the product are present at delivery.

Reference SOP CTP9824, *Monitoring and Measurement of Product*

8.3 Control of Nonconforming Product

CTP ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure is established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

CTP's documented procedure defines the responsibility and authority for the review and disposition of nonconforming product, and the process for approving personnel making these decisions.

Where applicable, CTP deals 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. CTP's nonconforming product control process provides for timely reporting of delivered nonconforming product;
e) by taking actions necessary to contain the effect of the nonconformity on other processes or products.

Dispositions of use-as-is or repair are only used after approval by an authorized representative of the organization responsible for design.

CTP does not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if the nonconformity results in a departure from the contract requirements.

Product dispositioned for scrap are conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

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

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained (see 4.2.4).

Reference SOP CTP9830, *Control of Nonconforming Product*

8.4 Analysis of Data

CTP determines, collects and analyzes 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 includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to

a) customer satisfaction (see 8.2.1),
b) conformity to product requirements (see 8.2.4),
c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and
d) suppliers (see 7.4).

8.5 Improvement

8.5.1 Continual Improvement

CTP continually improves 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.

CTP monitors the implementation of improvement activities and evaluates the effectiveness of the results.

8.5.2 Corrective Action

CTP takes action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure is 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 (see 4.2.4)
f) reviewing the effectiveness of the corrective action taken,

g) flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity,
h) specific actions where timely and/or effective corrective actions are not achieved, and
i) determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.

Reference SOP CTP9852, *Corrective Action*

8.5.3 Preventive Action

CTP determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure is 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 (see 4.2.4), and
e) reviewing the effectiveness of the preventive action taken.

Reference SOP CTP9853, *Preventive Action*

CHANGE HISTORY		
REVISION	**DESCRIPTION**	**DATE**
G	Rewritten to meet AS9100C requirements.	04/16/2014