CUSTOM TUBE PRODUCTS, INC.

CTP1000

Quality Manual

Revision H

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1. Introduction and Scope

Custom Tube Products, Inc. (CTP) is a manufacturing company located in Edgewater, Florida specializing in precision tube fabrications and machining. CTP produces products for aviation, medical, industrial, and commercial customers. CTP specializes in medium-to-high volume production of fabricated products ranging from simple bent tubes to complex assemblies.

Scope of the Quality Management System

CTP's quality management system is designed to meet all the requirements of the ISO 9001:2015 standard excluding design.

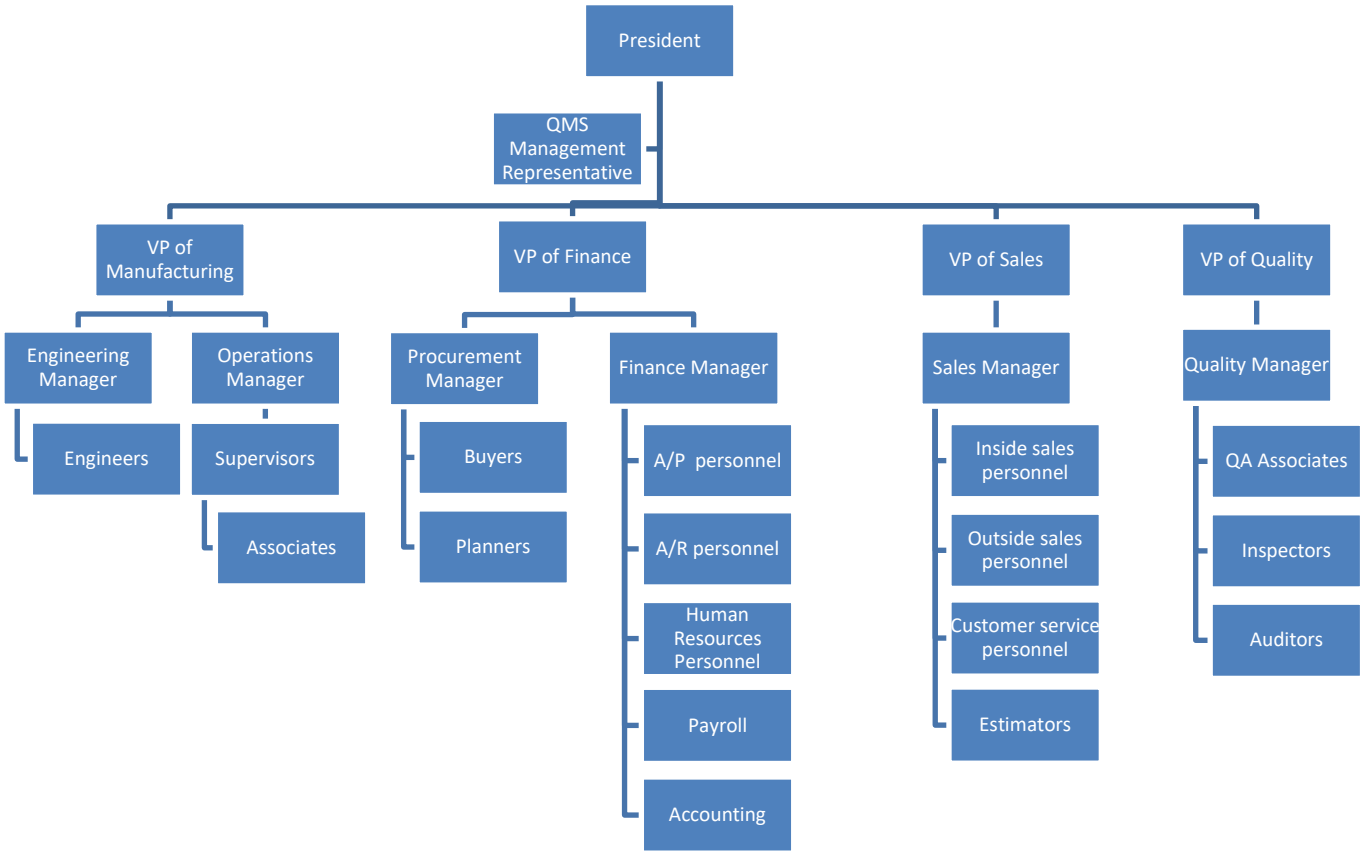

Figure 1. Custom Tube Products Organizational Chart

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. the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;
b. facilitating opportunities to enhance customer satisfaction;
c. addressing risks and opportunities associated with its context and objectives;
d. the ability to demonstrate conformity to specified quality management system requirements.

3. Terms and Definitions

3.1 Counterfeit Part

An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer.

3.2 Critical Items

Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the provision and use of the products and services; 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.

3.3 Key Characteristic

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

3.4 Product Safety

The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

3.5 Special Requirements

Those requirements identified by the customer, or determined by the organization, which have high risks of not being met, thus requiring their inclusion in the operational 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 the organization to be at the limit of its technical or process capabilities.

4. Context of the Organization

4.1 Understanding the Organization and Its Context

CTP has determined external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

CTP monitors and reviews information about these external and internal issues.

4.2 Understanding the Needs and Expectations of Interested Parties

Due to their effect or potential effect on CTP's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, CTP has determined:

a. the interested parties that are relevant to the quality management system;

b. the requirements of these interested parties that are relevant to the quality management system.

CTP monitors and reviews information about these interested parties and their relevant requirements.

CTP defines all customers and vendors/suppliers that produce or/are present in the final product as interested parties.

4.3 Determining the Scope of the Quality Management System

CTP has determined the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, CTP considered:

a. the external and internal issues referred to in 4.1;

b. the requirements of relevant interested parties referred to in 4.2;

c. the products and services of the organization.

CTP applies all the requirements of the ISO 9001 Standard if they are applicable within the determined scope of its quality management system.

CTP's quality management system is available and maintained as documented information. CTP's scope states the types of products and services covered, and provides justification for any requirement of the ISO 9001 Standard that the organization determines is not applicable to the scope of its quality management system.

4.4 Quality Management System and Its Processes

4.4.1

CTP has established, implemented, maintained, and continually improves a quality management system, including the processes needed and their interactions, in accordance with the requirements of the ISO 9001 Standard.

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

CTP has determined the processes needed for the quality management system and their application throughout the organization, and has:

a. determined the inputs required and the outputs expected from these processes;

b. determined the sequence and interaction of these processes;

c. determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;

d. determined the resources needed for these processes and ensure their availability;

e. assigned the responsibilities and authorities for these processes;

f. addressed the risks and opportunities as determined in accordance with the requirements of 6.1;

g. evaluated these processes and implemented any changes needed to ensure that these processes achieve their intended results;

h. improved the processes and the quality management system.

4.4.2

To the extent necessary, CTP has:

a. maintained documented information to support the operation of its processes;

b. retained documented information to have confidence that the processes are being carried out as planned.

CTP has established and maintained documented information that includes:

− a general description of relevant interested parties (see 4.2 a);

− the scope of the quality management system, including boundaries and applicability (see 4.3);

− a description of the processes needed for the quality management system and their application throughout the organization;

− the sequence and interaction of these processes;

− assignment of the responsibilities and authorities for these processes.

5. Leadership

5.1 Leadership and Commitment

5.1.1 General

Top management demonstrates leadership and commitment with respect to the quality management system by:

a. taking accountability for the effectiveness of the quality management system;

b. ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;

c. ensuring the integration of the quality management system requirements into the organization's business processes;

d. promoting the use of the process approach and risk-based thinking;

e. ensuring that the resources needed for the quality management system are available;

f. communicating the importance of effective quality management and of conforming to the quality management system requirements;

g. ensuring that the quality management system achieves its intended results;

h. engaging, directing, and supporting persons to contribute to the effectiveness of the quality management system;

i. promoting improvement;

j. supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer Focus

Top management demonstrates leadership and commitment with respect to customer focus by ensuring that:

a. customer and applicable statutory and regulatory requirements are determined, understood, and consistently met;

b. the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c. the focus on enhancing customer satisfaction is maintained;

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

5.2 Policy

5.2.1 Establishing the Quality Policy

Top management has established, implemented, and maintained a quality policy that:

a. is appropriate to the purpose and context of the organization and supports its strategic direction;

b. provides a framework for setting quality objectives;

c. includes a commitment to satisfy applicable requirements;

d. includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the Quality Policy

CTP's quality policy is:

a. available and maintained as documented information;

b. communicated, understood, and applied within the organization;

c. available to relevant interested parties, as appropriate.

5.3 Organizational Roles, Responsibilities and Authorities

Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization.

Top management has assigned the responsibility and authority for:

a. ensuring that the quality management system conforms to the requirements of the ISO 9001 Standard;

b. ensuring that the processes are delivering their intended outputs;

c. reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;

d. ensuring the promotion of customer focus throughout the organization;

e. ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Top management has appointed the Quality Manager, identified as the management representative, who has the responsibility and authority for oversight of the above requirements.

The Quality Manager has the organizational freedom and unrestricted access to top management to resolve quality management issues.

6. Planning

6.1 Actions to Address Risks and Opportunities

6.1.1

When planning for the quality management system, CTP has considered the issues referred to in 4.1 and the requirements referred to in 4.2 and determined the risks and opportunities that needed to be addressed to:

a. give assurance that the quality management system can achieve its intended result(s);

b. enhance desirable effects;

c. prevent, or reduce, undesired effects;

d. achieve improvement.

6.1.2

CTP has planned:

a. actions to address these risks and opportunities;

b. how to:

1. integrate and implement the actions into its quality management system processes (see 4.4);

2. evaluate the effectiveness of these actions.

The actions taken to address risks and opportunities have been proportionate to the potential impact on the conformity of products and services.

6.2 Quality Objectives and Planning to Achieve Them

6.2.1

CTP has established quality objectives at relevant functions, levels, and processes needed for the quality management system.

The quality objectives are:

a. consistent with the quality policy;

b. measurable;

c. taken into account applicable requirements;

d. relevant to conformity of products and services and to enhancement of customer satisfaction;

e. monitored;

f. communicated;

g. updated, as appropriate.

CTP maintains documented information on the quality objectives.

6.2.2

When planning how to achieve its quality objectives, CTP has determined:

a. what will be done;

b. what resources will be required;

c. who will be responsible;

d. when it will be completed;

e. how the results will be evaluated.

6.3 Planning of Changes

When CTP determines the need for changes to the quality management system, the changes are carried out in a planned manner (see 4.4).

CTP considers:

a. the purpose of the changes and their potential consequences;

b. the integrity of the quality management system;

c. the availability of resources;

d. the allocation or reallocation of responsibilities and authorities.

7. Support

7.1 Resources

7.1.1 General

CTP has determined and provides the resources needed for the establishment, implementation, maintenance, and continual improvement of the quality management system.

CTP considers:

a. the capabilities of, and constraints on, existing internal resources;

b. what needs to be obtained from external providers.

7.1.2 People

CTP has determined and provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

CTP has determined, provided, and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

7.1.4 Environment for the Operation of Processes

CTP has determined, provided, and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

CTP has determined and provides the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

CTP ensures that the resources provided:

a. are suitable for the specific type of monitoring and measurement activities being undertaken;

b. are maintained to ensure their continuing fitness for their purpose.

CTP retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement Traceability

CTP considers measurement traceability a requirement, and is an essential part of providing confidence in the validity of measurement 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; when no such standards exist, the basis used for calibration or verification will be retained as documented information;

b. identified in order to determine their status;

c. safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results.

CTP has established, implemented, and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification.

CTP maintains a register of the monitoring and measuring equipment. The register includes the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.

Calibration or verification of monitoring and measuring equipment is carried out under suitable environmental conditions (see 7.1.4).

CTP determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and takes appropriate action as necessary.

7.1.6 Organizational Knowledge

CTP has determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge is maintained and is made available to the extent necessary.

When addressing changing needs and trends, CTP considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

CTP:

a. determines the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

b. ensures that these persons are competent on the basis of appropriate education, training, or experience;

c. where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

d. retains appropriate documented information as evidence of competence.

7.3 Awareness

CTP ensures that persons doing work under the organization's control are aware of:

a. the quality policy;

b. relevant quality objectives;

c. their contribution to the effectiveness of the quality management system, including the benefits of improved performance;

d. the implications of not conforming with the quality management system requirements;

e. relevant quality management system documented information and changes thereto;

f. their contribution to product or service conformity;

g. their contribution to product safety;

h. the importance of ethical behavior.

7.4 Communication

CTP has determined the internal and external communications relevant to the quality management system, including:

a. on what it will communicate;

b. when to communicate;

c. with whom to communicate;

d. how to communicate;

e. who communicates.

7.5 Documented Information

7.5.1 General

CTP's quality management system includes:

a. documented information required by the ISO 9001 Standard;

b. documented information determined by CTP as being necessary for the effectiveness of the quality management system.

7.5.2 Creating and Updating

When creating and updating documented information, CTP ensures appropriate:

a. identification and description (e.g., a title, date, author, or reference number);

b. format (e.g., language, software version, graphics) and media (e.g., paper, electronic);

c. review and approval for suitability and adequacy.

7.5.3 Control of Documented Information

7.5.3.1

Documented information required by the quality management system and by the ISO 9001 Standard will be controlled to ensure:

a. it is available and suitable for use, where and when it is needed;

b. it is adequately protected (e.g., from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2

For the control of documented information, CTP has addressed the following activities, as applicable:

a. distribution, access, retrieval, and use;

b. storage and preservation, including preservation of legibility;

c. control of changes (e.g., version control);

d. retention and disposition;

e. prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

Documented information of external origin determined by CTP to be necessary for the planning and operation of the quality management system will be identified as appropriate, and be controlled.

Documented information retained as evidence of conformity is protected from unintended alterations.

When documented information is managed electronically, data protection processes are defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage).

8. Operation

8.1 Operational Planning and Control

CTP plans, implements, and controls the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in clause 6, by:

a. determining the requirements for the products and services;

b. establishing criteria for:

1. the processes;

2. the acceptance of products and services;

c. determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services;

d. implementing control of the processes in accordance with the criteria;

e. determining, maintaining, and retaining documented information to the extent necessary:

1. to have confidence that the processes have been carried out as planned;

2. to demonstrate the conformity of products and services to their requirements;

f. determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;

g. engaging representatives of affected organization functions for operational planning and control;

h. determining the process and resources to support the use and maintenance of the products and services;

i. determining the products and services to be obtained from external providers;

j. establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

As appropriate to the organization, customer requirements, and products and services, CTP plans and manages product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints.

CTP controls planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

CTP ensures that outsourced processes are controlled (see 8.4).

CTP has established, implemented, and maintains a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements. The process ensures that work transfer impacts and risks are managed.

8.1.1 Operational Risk Management

CTP plans, implements, and controls a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to the organization and the products and services:

a. assignment of responsibilities for operational risk management;

b. definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);

c. identification, assessment, and communication of risks throughout operations;

d. identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;

e. acceptance of risks remaining after implementation of mitigating actions.

8.1.2 Configuration Management

CTP plans, implements, and controls a process for configuration management as appropriate to the organization and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process:

a. controls product identity and traceability to requirements, including the implementation of identified changes;

b. ensures that the documented information (e.g., requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services.

8.1.3 Product Safety

CTP plans, implements, and controls the processes needed to assure product safety during the entire product life cycle, as appropriate to the organization and the product.

8.1.4 Prevention of Counterfeit Parts

CTP plans, implements, and controls processes, appropriate to the organization and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Communication with customers include:

a. providing information relating to products and services;

b. handling enquiries, contracts, or orders, including changes;

c. obtaining customer feedback relating to products and services, including customer complaints;

d. handling or controlling customer property;

e. establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the Requirements for Products and Services

When determining the requirements for the products and services to be offered to customers, CTP ensures that:

a. the requirements for the products and services are defined, including:

1. any applicable statutory and regulatory requirements;

2. those considered necessary by the organization;

b. the organization can meet the claims for the products and services it offers;

c. special requirements of the products and services are determined;

d. operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified.

8.2.3 Review of the Requirements for Products and Services

8.2.3.1

CTP ensures that it has the ability to meet the requirements for products and services to be offered to customers. CTP conducts a review before committing to supply products and services to the customer, to include:

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 the specified or intended use, when known;

c. requirements specified by CTP;

d. statutory and regulatory requirements applicable to the products and services;

e. contract or order requirements differing from those previously expressed.

If upon review CTP determines that some customer requirements cannot be met or can only partially be met, CTP shall negotiate a mutually acceptable requirement with the customer.

CTP ensures that contract or order requirements differing from those previously defined are resolved.

The customer requirements will be confirmed by a CTP appointed Customer Representative before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.2

CTP retains documented information, as applicable:

a. on the results of the review;

b. on any new requirements for the products and services.

8.2.4 Changes to Requirements for Products and Services

CTP ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and Development of Products and Services

CTP is a contract manufacturer and does not design and develop the products we sell. As such, CTP takes exception to section 8.3, Design and Development of Products and Services.

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General

CTP ensures that externally provided processes, products, and services conform to requirements.

CTP is responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.

CTP ensures, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.

CTP will identify and manage the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers.

CTP requires that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.

CTP has determined the controls to be applied to externally provided processes, products, and services when:

a. products and services from external providers are intended for incorporation into CTP's own products and services;

b. products and services are provided directly to the customer(s) by external providers on behalf of CTP;

c. a process, or part of a process, is provided by an external provider as a result of a decision by CTP.

CTP has determined and applied criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. CTP retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.1.1

CTP has:

a. defined the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;

b. maintained a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);

c. periodically reviewed external provider performance including process, product and service conformity, and on-time delivery performance;

d. defined the necessary actions to take when dealing with external providers that do not meet requirements;

e. defined the requirements for controlling documented information created by and/or retained by external providers.

8.4.2 Type and Extent of Control

CTP ensures that externally provided processes, products, and services do not adversely affect CTP's ability to consistently deliver conforming products and services to its customers.

CTP:

a. ensures that externally provided processes remain within the control of its quality management system;

b. defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

c. takes into consideration:

1. the potential impact of the externally provided processes, products, and services on CTP's ability to consistently meet customer and applicable statutory and regulatory requirements;

2. the effectiveness of the controls applied by the external provider;

3. the results of the periodic review of external provider performance (see 8.4.1.1 c);

d. determining the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements.

Verification activities of externally provided processes, products, and services are performed according to the risks identified by the CTP. These include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.

8.4.3 Information for External Providers

CTP ensures the adequacy of requirements prior to their communication to the external provider.

CTP communicates to external providers its requirements for:

a. the processes, products, and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions);

b. the approval of:

1. products and services;

2. methods, processes, and equipment;

3. the release of products and services;

c. competence, including any required qualification of persons;

d. the external providers' interactions with CTP;

e. control and monitoring of the external providers' performance to be applied by CTP;

f. verification or validation activities that CTP, or its customer, intends to perform at the external providers' premises;

g. design and development control;

h. special requirements, critical items, or key characteristics;

i. test, inspection, and verification (including production process verification);

j. the use of statistical techniques for product acceptance and related instructions for acceptance by CTP;

k. the need to:

− implement a quality management system;

− use customer-designated or approved external providers, including process sources (e.g., special processes);

− notify CTP of nonconforming processes, products, or services and obtain approval for their disposition;

− prevent the use of counterfeit parts (see 8.1.4);

− notify CTP of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain CTP's approval;

− flow down to external providers applicable requirements including customer requirements;

− provide test specimens for design approval, inspection/verification, investigation, or auditing;

− retain documented information, including retention periods and disposition requirements;

l. the right of access by CTP, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;

m. ensuring that persons are aware of:

− their contribution to product or service conformity;

− their contribution to product safety;

− the importance of ethical behavior.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

CTP has implemented production and service provisions under controlled conditions.

Controlled conditions include, as applicable:

a. the availability of documented information that defines:

1. the characteristics of the products to be produced, the services to be provided, or the activities to be performed;

2. the results to be achieved;

b. the availability and use of suitable monitoring and measuring resources;

c. the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

1. ensuring that documented information for monitoring and measurement activity for product acceptance includes:

− criteria for acceptance and rejection;

− where in the sequence verification operations are to be performed;

− measurement results to be retained (at a minimum an indication of acceptance or rejection);

− any specific monitoring and measurement equipment required and instructions associated with their use;

2. ensuring that when sampling is used 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).

d. the use of suitable infrastructure and environment for the operation of processes;

e. the appointment of competent persons, including any required qualification;

f. the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g. the implementation of actions to prevent human error;

h. the implementation of release, delivery, and post-delivery activities;

i. the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);

j. the accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);

k. the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;

l. the determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);

m. the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;

n. the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;

o. the provision for the prevention, detection, and removal of foreign objects;

p. the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (see 7.1.3);

q. the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.

8.5.1.1 Control of Equipment, Tools, and Software Programs

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes are validated prior to final release for production and are maintained.

Storage requirements are defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

8.5.1.2 Validation and Control of Special Processes

For processes where the resulting output cannot be verified by subsequent monitoring or measurement, CTP has established arrangements for these processes including, as applicable:

a. definition of criteria for the review and approval of the processes;

b. determination of conditions to maintain the approval;

c. approval of facilities and equipment;

d. qualification of persons;

e. use of specific methods and procedures for implementation and monitoring the processes;

f. requirements for documented information to be retained.

8.5.1.3 Production Process Verification

CTP has implemented production process verification activities to ensure the production process is able to produce products that meet requirements.

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 able to produce parts and assemblies that meet requirements. This activity is repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes). This activity is referred to as First Article Inspection (FAI).

CTP retains documented information on the results of production process verification.

8.5.2 Identification and Traceability

CTP uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

CTP maintains the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

CTP identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

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

CTP controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability.

8.5.3 Property Belonging to Customers or External Providers

CTP exercises care with property belonging to customers or external providers while it is under CTP's control or being used by CTP.

CTP identifies, verifies, protects, and safeguards customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged, or otherwise found to be unsuitable for use, CTP reports this to the customer or external provider and retain documented information on what has occurred.

8.5.4 Preservation

CTP preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

Preservation of outputs also include, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:

a. cleaning;

b. prevention, detection, and removal of foreign objects;

c. special handling and storage for sensitive products;

d. marking and labeling, including safety warnings and cautions;

e. shelf life control and stock rotation;

f. special handling and storage for hazardous materials.

8.5.5 Post-Delivery Activities

CTP manufactures components to customer's designs and does not perform any design activities.

In determining the extent of post-delivery activities that are required, CTP considers:

a. customer requirements;

b. customer feedback;

c. defects in workmanship;

When problems are detected after delivery, CTP will take appropriate action including investigation and reporting. Post delivery activities are managed through the RMA (Return Material Authorization) process.

8.5.6 Control of Changes

CTP reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

CTP retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of Products and Services

CTP has implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer will not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

CTP retains documented information on the release of products and services. The documented information includes:

a. evidence of conformity with the acceptance criteria;

b. traceability to the person(s) authorizing the release.

When required to demonstrate product qualification, CTP ensures that retained documented information provides evidence that the products and services meet the defined requirements.

CTP ensures that all documented information required to accompany the products and services are present at delivery.

8.7 Control of Nonconforming Outputs

8.7.1

CTP ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

CTP takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, during or after the provision of services.

CTP's nonconformity control process is maintained as documented information including the provisions for:

− defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;

− taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;

− timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;

− defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).

CTP deals with nonconforming outputs in 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 by a relevant authority and, when applicable, by the customer.

Dispositions of use-as-is or repair for the acceptance of nonconforming products will only be implemented:

− after authorization by the customer, if the nonconformity results in a departure from the contract requirements.

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

Counterfeit, or suspect counterfeit, parts are controlled to prevent reentry into the supply chain.

Conformity to the requirements are verified when nonconforming outputs are corrected.

8.7.2
CTP retains documented information that:

a. describes the nonconformity;

b. describes the actions taken;

c. describes any concessions obtained;

d. identifies the authority deciding the action in respect of the nonconformity.

9. Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General
CTP has determined:

a. what needs to be monitored and measured;

b. the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results;

c. when the monitoring and measuring shall be performed;

d. when the results from monitoring and measurement shall be analyzed and evaluated.

CTP evaluates the performance and the effectiveness of the quality management system.

CTP retains appropriate documented information as evidence of the results.

9.1.2 Customer Satisfaction
CTP monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. CTP determines the methods for obtaining, monitoring, and reviewing this information.

9.1.3 Analysis and Evaluation
CTP analyzes and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis are used to evaluate:

a. conformity of products and services;

b. the degree of customer satisfaction;

c. the performance and effectiveness of the quality management system;

d. if planning has been implemented effectively;

e. the effectiveness of actions taken to address risks and opportunities;

f. the performance of external providers;

g. the need for improvements to the quality management system.

9.2 Internal Audit

9.2.1

CTP conducts internal audits at planned intervals to provide information on whether the quality management system;

a. conforms to:

1. CTP's own requirements for its quality management system;

2. the requirements of ISO 9001:2015 Standard;

b. is effectively implemented and maintained.

9.2.2

CTP has:

a. planned, established, implemented, and maintains an audit program(s) including the frequency, methods, responsibilities, planning requirements, and reporting, which shall take into consideration the importance of the processes concerned, changes affecting CTP, and the results of previous audits;

b. defined the audit criteria and scope for each audit;

c. selected auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

d. ensured that the results of the audits are reported to relevant management;

e. taken appropriate correction and corrective actions without undue delay;

f. retained documented information as evidence of the implementation of the audit program and the audit results.

9.3 Management Review

9.3.1 General

Top management reviews CTP's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of the organization.

9.3.2 Management Review Inputs

The management review is planned and carried out taking into consideration:

a. the status of actions from previous management reviews;

b. changes in external and internal issues that are relevant to the quality management system;

c. information on the performance and effectiveness of the quality management system, including trends in:

1. customer satisfaction and feedback from relevant interested parties;

2. the extent to which quality objectives have been met;

3. process performance and conformity of products and services;

4. nonconformities and corrective actions;

5. monitoring and measurement results;

6. audit results;

7. the performance of external providers;

8. on-time delivery performance;

d. the adequacy of resources;

e. the effectiveness of actions taken to address risks and opportunities (see 6.1);

f. opportunities for improvement.

9.3.3 Management Review Outputs

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

a. opportunities for improvement;

b. any need for changes to the quality management system;

c. resource needs;

d. risks identified.

CTP retains documented information as evidence of the results of management reviews.

10. Improvement

10.1 General

CTP determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

These include:

a. improving products and services to meet requirements as well as to address future needs and expectations;

b. correcting, preventing, or reducing undesired effects;

c. improving the performance and effectiveness of the quality management system.

10.2 Nonconformity and Corrective Action

10.2.1

When a nonconformity occurs, including any arising from complaints, CTP:

a. reacts to the nonconformity and, as applicable:

1. take action to control and correct it;

2. deal with the consequences;

b. evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1. reviewing and analyzing the nonconformity;

2. determining the causes of the nonconformity, including, as applicable, those related to human factors;

3. determining if similar nonconformities exist, or could potentially occur;

c. implements any action needed;

d. reviews the effectiveness of any corrective action taken;

e. updates risk(s) and opportunities determined during planning, if necessary;

f. makes changes to the quality management system, if necessary;

g. flows down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;

h. takes specific actions when timely and effective corrective actions are not achieved.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

CTP maintains documented information that defines the nonconformity and corrective action management processes.

10.2.2

CTP retains documented information as evidence of:

a. the nature of the nonconformities and any subsequent actions taken;

b. the results of any corrective action.

10.3 Continual Improvement

CTP continually improves the suitability, adequacy, and effectiveness of the quality management system.

CTP considers the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

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

CHANGE HISTORY

REVISION	DESCRIPTION	DATE
G	Rewritten to meet AS9100C requirements.	04/16/2014
H	Rewritten to meet AS9100D requirements.	03/26/2020
