Cartel Electronics

AS 9100 Quality Systems Manual

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Placentia, California 92870

Introduction

Cartel Electronics, as a global supplier to the aviation, space, and space industries, has developed and implemented a Quality Management System in order to document the company's best business practices, to meet or exceed the requirements and expectations of its customers and applicable statutory and regulatory requirements, continually improve the quality, reliability, and safety or our products, and improve the overall effectiveness of the management of the company.

The Quality Management System of Cartel Electronics meets the requirements of the international standard SAE AS 9100.

The manual is divided into eight sections that correlate to the Quality Management System sections of the ISO 9001:2008 format and AS 9100 C. Each section begins with a policy statement expressing Cartel Electronics' obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the AS 9100 standard that must be met and maintained in order to ensure customer satisfaction, manage changes to the overall business environment to assess and mitigate risk, foster continuous improvement, and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals to demonstrate our ability to meet requirements, and adhere to statutory and regulatory requirements applicable to our products. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

President: _____

Process approach:

In order to function effectively, Cartel Electronics has determined and manages all of the interlinked activities that make up the organization. Collectively, these activities or processes are controlled to produce desired outcomes. To achieve this end, Cartel Electronics:

a. Understands and strives to meet customer, business, and regulatory requirements.
b. Considers processes in terms of added value
c. Continually monitors process inputs and outputs to assess their performance, quality, and effectiveness
d. Takes corrective and preventive actions based on objective measurements to ensure desired outcomes are met
e. Establishes goals and objectives based on all of the above.

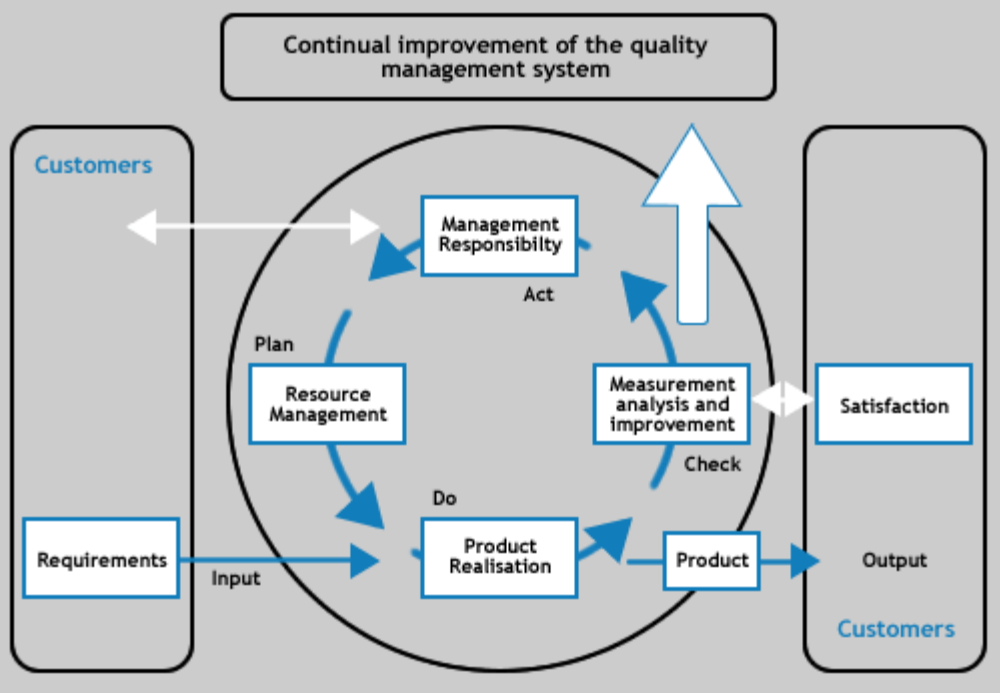
Cartel Electronics has adopted the Plan-Do-Check-Act model to describe its approach to process management:

Plan: establish the objective and processes necessary to deliver results in accordance with customer requirements

Do: Implement the process

Check: Monitor and measure processes and product against policies, objectives and requirements; report the results.

Act: Take actions to continually improve process performance.

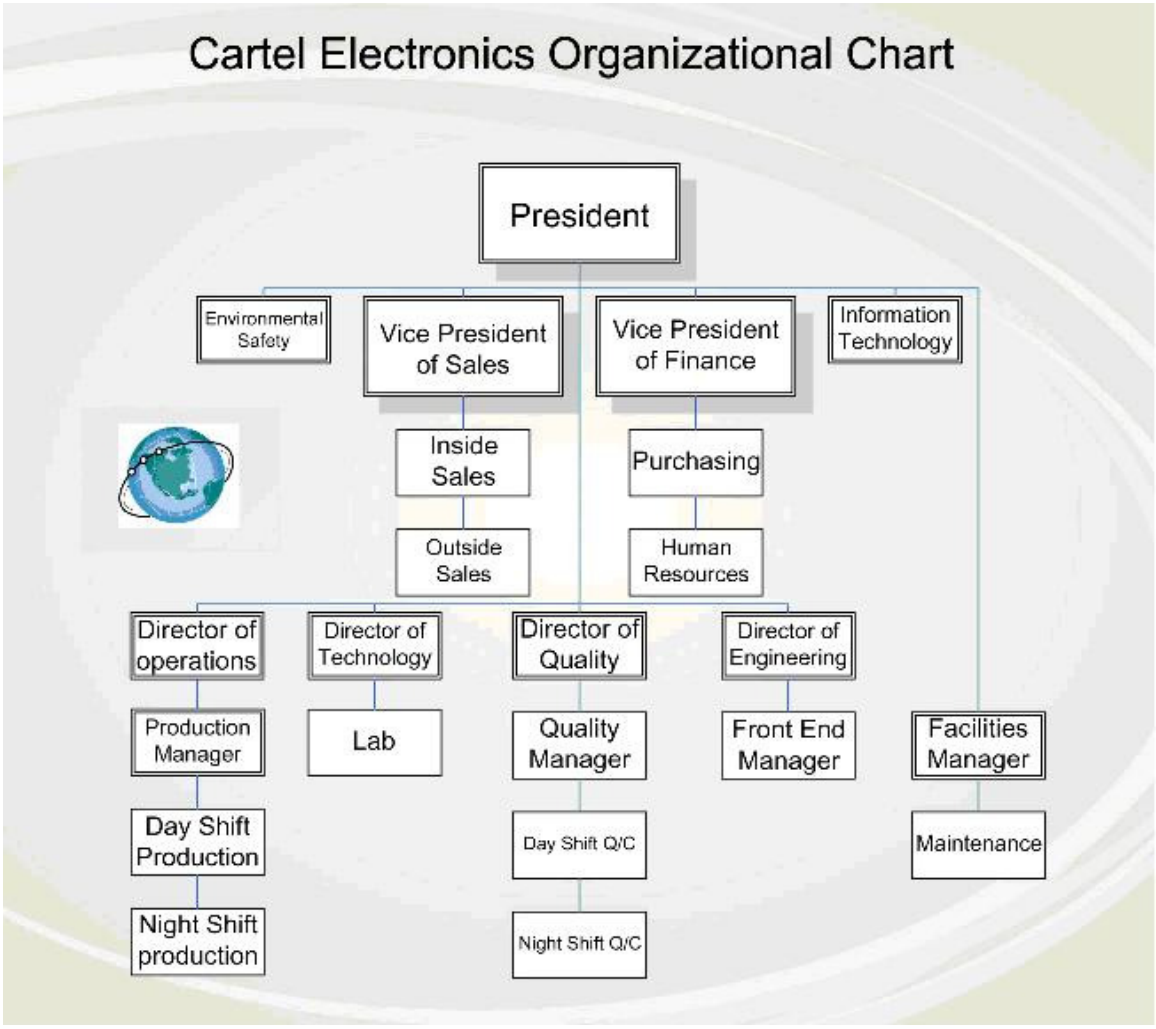


Quality Manual Distribution

The Quality Manual shall be distributed to the following:

President,
VP Sales,
VP Finance / Human Resources,
Director of Technology,
Management Representative
Engineering Manager,
Quality Manager,
Environmental/Safety Manager,
Facilities Manager
Purchasing,
Production Control,
Shipping Department,
Receiving Department,
Manufacturing,
Human Resources,
Receiving Inspection,

In process Inspection,
Final Inspection,
Laboratory.


Cartel Electronics Organizational Chart
President
Environmental Safety
Vice President of Sales
Vice President of Finance
Information Technology
Inside Sales
Outside Sales
Purchasing
Human Resources
Director of operations
Director of Technology
Director of Quality
Director of Engineering
Production Manager
Lab
Quality Manager
Front End Manager
Facilities Manager
Day Shift Production
Night Shift production
Day Shift Q/C
Night Shift Q/C
Maintenance

Cartel Electronics Inc. Organization Authorities Matrix									
President	President	VP Sales	VP Finances	Director Quality	Director Technology	Director Engineering	Facilities Manager	Production Manager	Quality Manager
Calibration & Verification				x					
Certificates of Conformance									x
Control of Nonconforming Material									x
Corrective/Preventive Action System				x					
Customer Communication		x							
Customer Contracts		x							
Configuration Control						x			
Planning/Cam						x			
Document Control				x					
Final Inspection									x
Financials			x						
ITAR Compliance				x					
Generates Process Sheets					x				
Human Resources			x						
In-Process Inspection									x
Internal Audits				x					
External audits				x					
Management Representative				x					
Management Review Meeting				x					
Facilities/Maintenance							x		
Process Development					x				
Production								x	
Purchasing			x						
Quality Assurance				x					
QualityControl				x					
Quality Management System				x					
Quality Objectives	x								
Quality Policy	x								
Quote	x								
Records Control				x					
Sales		x							
Sales & Marketing		x							
Shipping Documents								x	
Supplier Evaluations				x					
System Training				x					
Training				x					

AS9100/Cartel QMS Clause Cross Reference Index

AS-9100-C Clause	Cartel Quality Manual AP-422 Clause	Related Procedure
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4.2 Documentation Requirements	4.2	AP-422
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4.2.2 Quality Manual	4.2.2	AP-422
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5.0 Management Responsibility	5	AP-500 Mgmt Responsibility
5.1 Management Commitment	5.1	AP-500 Mgmt Responsibility
5.2 Customer Focus	5.2	SP-720 Customer Related Processes
5.3 Quality Policy	5.3	AP-501 Quality Policy
5.4 Planning	5.4	AP-500 Mgmt Responsibility
5.4.1 Quality Objectives	5.4.1	AP-500 Mgmt Responsibility
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5.6 Management Review	5.6	AP-500 Mgmt Responsibility
5.6.1 General	5.6.1	AP-500 Mgmt Responsibility
5.6.2 Review Input	5.6.2	AP-500 Mgmt Responsibility
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AS-9100-C Clause	**Cartel Quality Manual AP-422 Clause**	**Related Procedure**

6.0 Resource Management	6	AP-500 Mgmt Responsibility
6.1 Provision of Resources	6.1	AP-500 Mgmt Responsibility
6.2 Human Resources	6.2	AP-622 Competence, Awareness and Training
6.3 Infrastructure	6.3	EP-630 Infrastructure
6.4 Work Environment	6.4	EP-630 Infrastructure
7.0 Product Realization	7	AP-422
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7.2.1 Determination of Requirements Related to the Product	7.2.1	SP-720 Customer Related Processes
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7.4.1 Purchasing Process	7.4.1	AP-740 Purchasing
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7.5.1.1 Production Process Verification	7.5.1.1	MP-750 Control of Production and Service Provision

AS-9100-cClause	**Cartel Quality Manual AP-422 Clause**	**Related Procedure**
7.5.1.2 Control of Production Process Changes	7.5.1.2	MP-750 Control of Production and Service Provision
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AS-9100-C Clause	Cartel Quality Manual AP-422 Clause	Related Procedure
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8.5.1 Continual Improvement	8.5.1	AP-500 Mgmt Responsibility
8.5.2 Corrective Action	8.5.2	QP-852 Quality Action Requests
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Section 1: Scope

1.1 General

The quality manual outlines the policies, procedures and requirements of the Quality Management System. The system is structured to comply with the conditions set forth in the International Standard SAE AS 9100 C and ISO 9001:2008. In the event of conflict between this quality manual and contractual, statutory, or regulatory requirement, the later shall take precedence.

The application of this manual demonstrates our ability to consistently provide products that meet customer and applicable statutory and regulatory requirements.

This quality system is designed to enhance customer satisfaction by including processes for the continual improvement of our products and services.

1.2 Application

Cartel Electronics has determined that the following requirements are not applicable to the operations at this site and are documented as exclusions:

- Design and Development (SAE AS9100 Rev C Section 7.3)
    - Cartel Electronics manufactures bare printed circuit boards to customers' designs. Design and development processes are not applicable to Cartel Electronics.
- **Service provisions - exclusion**
- Cartel Electronics manufactures bare printed circuit boards to customers. Servicing is not applicable to Cartel Electronics. Section 2: Normative Reference

2.0 Quality Management System References

The following documents were used as reference during the preparation of the Quality Management System:

- American National Standard ANSI/AS 9001/ASQ Q9000-2008 Quality Management Systems - Vocabulary.
- American National Standard ANSI/AS 9001/ASQ Q9001-2008, Quality Management Systems – Requirements
- American National Standard ANSI/AS 9001/ASQ Q9004-2008, Quality Management Systems – Guidelines for performance Improvements
- Society of Automotive Engineers SAE AS 9100C - Quality Management Systems – Requirements

Section 3: Terms and Definitions

3.0 Quality Management System Terms and Definitions

This section is for definitions unique to Cartel Electronics.

- Critical items – those features that have a significant effect on the functionality, performance, reliability, safety, etc. of our product. Critical items require specific controls or actions to ensure they are adequately managed and include: Plating thickness, line width, stack-up thickness, impedance, and surface adhesion.
- Customer owned property - Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.
- Customer supplied product - Any type of service or material supplied to be utilized in the manufacture, modification or repair of customer-owned property.
- Outsourced Process – a process that is needed for product realization or that is in support of the management of the quality system and is contracted to be performed by an external party.
- Product – The end item result of meeting all contract terms and conditions. (eg: manufactured goods)
- Process – An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs. Note: often the output from one process directly forms the input to the next process.
- Quality Records – Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable
- Key Characteristics- The features of a material, process, or part whose variation has a significant influence on product fit, performance, or producibility that require specific actions to control.
- Risk – An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.
- Special Requirements – Those requirements identified by the customer, or determined by Cartel Electronics which have a high probability of not being achieved, and must be considered in the risk management process. Special requirements include: product features near the edge of current process capabilities, tightened manufacturing tolerances, designs of significantly increased complexity, and /or have accelerated delivery commitments.
- Work Environment – those conditions under which work is performed including physical, environmental, and other factors such as noise, temperature, humidity, lighting, or weather.

Section 4

Quality Management System

4.1 General requirements

Cartel Electronics has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of AS 9100. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review, and addresses all customer, statutory and regulatory requirements.

To design and implement the QMS Cartel Electronics has:

- Determine the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the Quality Manual
- Determined the sequence and interaction of these processes, and illustrated them on the Process Flow Diagram
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective.
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes
- Established systems to monitor, measure – where applicable, and analyze these processes, and
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes

Outsourced processes and products are subject to the same requirements and controls as products made at Cartel Electronics, and are defined within the quality system. Cartel recognizes and accepts responsibility for the conformity and legal compliance of its outsourced process.

4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

- A documented Quality Policy
- Quality Objectives
- This Quality Manual
- Documented Procedures
- Documents identified as needed for the effective planning, operation and control of our processes, and
- Quality Records
- Records required by regulatory authorities.

Cartel Electronics ensures that personnel have access to quality management system documentation and are aware of relevant procedures and changes. We also provide customer or regulatory authorities access to quality management system documentation.

4.2.2 Quality manual

This Quality Manual has been prepared to describe Cartel Electronics' QMS. The scope and permissible exclusions of the QMS are described in section one of this manual. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section. The Process Flow Diagram at the end of section 4 provides a description of the interaction between the processes of the QMS system.

The relationship between the AS 9100 standard and documented procedure has been indicated by use of a numbering system that correlates to the AS 9100 standard.

4.2.3 Control of documents

All of the QMS documents are controlled according to the Document Control Procedure AP-423. This procedure defines the process for:

- Approving documents for adequacy prior to issue
- Reviewing and updating as necessary and re-approving documents
- Ensuring that changes and current revision status of documents are identified
- Ensuring that relevant versions of applicable documents are available at points of use
- Ensuring that documents remain legible and readily identifiable
- Ensuring that documents of external origin, that we have determined are necessary for the planning and operation of the QMS, are identified and their distribution controlled
- Preventing the unintended use of obsolete documents and applying suitable identification to them if they are retained for any purpose

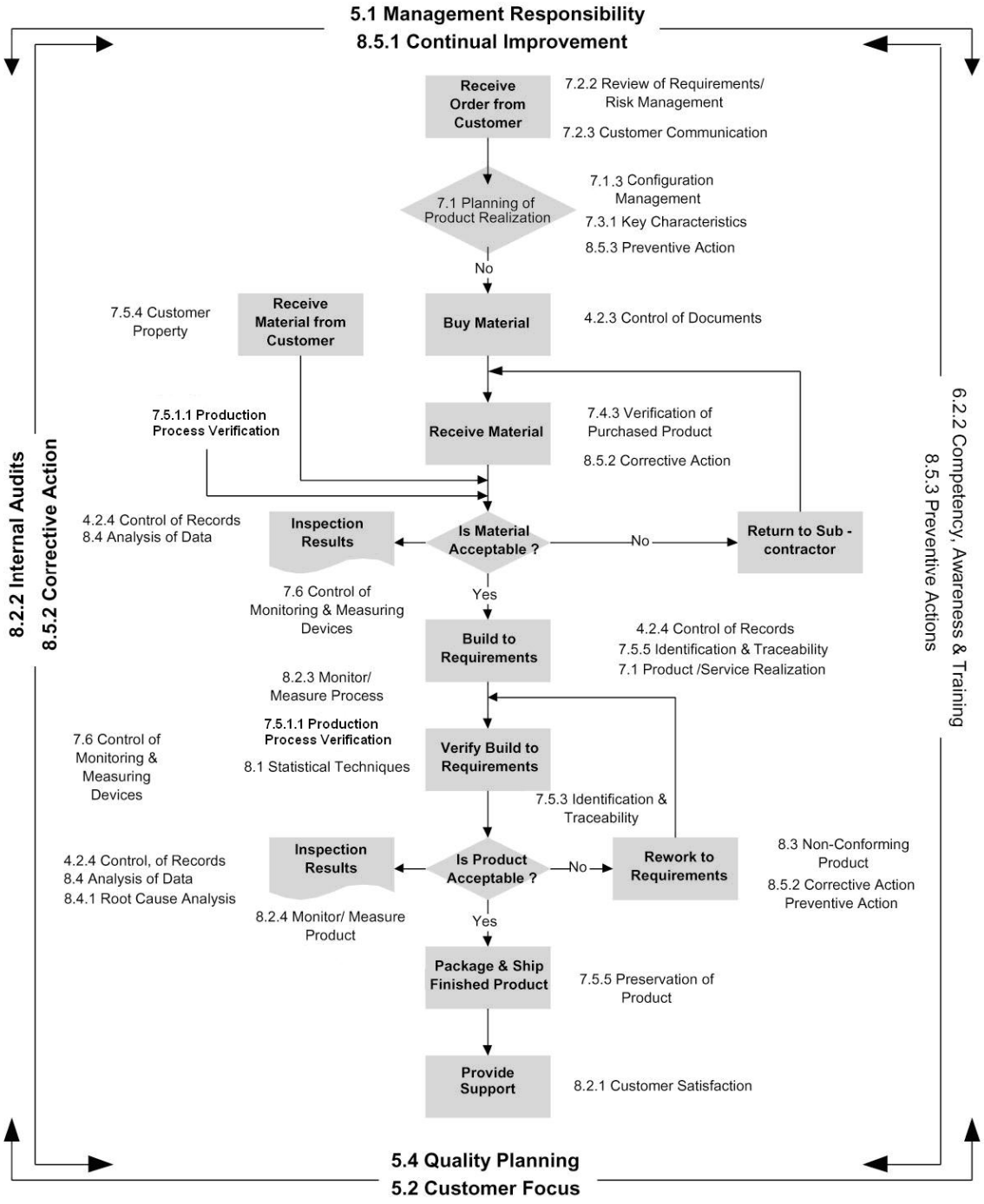
4.2.4 Control of quality records

Quality records are controlled and maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. The records, including those created by or maintained by suppliers, are maintained according to the Control of Quality Records Procedure AP-424. This procedure requires that quality records remain legible, readily identifiable and retrievable. The procedure defines the controls needed for identification, storage, protection, retrieval, retention time and disposition of quality records.

Related Procedures

Document Control	AP-423
Control of Quality Records	AP-424

AS9100 QMS System Diagram



Section 5

Management Responsibility

5.1 Management commitment

Top management has been actively involved in implementing the quality management system (QMS). It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

To continue to provide leadership and show commitment to the improvement of the QMS, management will do the following.

- Communicate the importance of meeting customer, statutory, and regulatory requirements.
- Establish quality objectives
- Establish the quality policy.
- Conduct quarterly management reviews.
- Ensure the availability of resources.

5.2 Customer focus

Cartel Electronics strives to identify current and future customer needs, to meet customer requirements and exceed customer expectations.

Top management ensures that customer requirements are understood and met, by requiring compliance with documented customer communication procedures. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people in our organization SP-720.

Top management ensures that product conformity and on-time delivery performance are measured, and that appropriate actions are taken when pre-determined results and objectives are not attained.

5.3 Quality policy

Top management ensures that the quality policy is communicated to all employees. It is included in new employee training and training on the QMS. It is posted in prominent places throughout the facility to maintain high standards within our organization.

Management reviews the quality policy at each management review meeting to determine the policy's continuing suitability for our organization. The Quality Policy is documented on AP-501, Quality Policy.

5.4 Planning

5.4.1 Quality objectives

Quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed annually for suitability. Objectives have been established for the following:

- Customer Satisfaction
- On-Time Delivery
- Product yield

Quality objectives are measurable, and reviewed against performance goals at each management review meeting per procedure AP-500 Mgmt Responsibility.

5.4.2 Quality management system planning

The quality system has been planned and implemented to meet our quality objectives and the requirements of 4.1 of the AS 9100 standard. Quality planning takes place as changes that affect the quality system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

An organizational chart has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions on the organizational chart. Job descriptions and the organizational chart are reviewed and approved by top management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities. An organizational chart is located on page 6 of this manual.

5.5.2 Management representative

The Cartel Electronics Director of Quality has been appointed by top management as management representative. As management representative, they have the following responsibility and authority:

- Ensure that processes needed for the quality management system are established and implemented.
- Report to top management on the performance of the quality management system, and note needed improvements.
- Promote awareness of customer requirements throughout the organization.
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS and

- Resolve matters pertaining to quality issues
- Organizational freedom and unrestricted access to top management to resolve matters pertaining to quality management.

5.5.3 Internal communication

Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS include department and management meetings, management review, circulation of minutes of management review meetings, Internal Audit Closing meetings, and other routine business communication per procedure AP-500 Mgmt Responsibility.

5.6 Management review

5.6.1 General

Per procedure AP-500 Mgmt Responsibility, top management reviews the QMS at minimum, bi-annually, (more frequently at management discretion) at management review meetings. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting.

5.6.2 Review input

Assessment of the QMS is based on a review of information inputs to management review. These inputs include the following:

- Results of audits
- Customer feedback
- Process performance and product conformity
- Company level quality data
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the quality management system
- Recommendations for improvement

5.6.3 Review output

During these review meetings, management will identify appropriate actions to be taken regarding the following issues:

- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements

- Resource needs

Responsibility for required actions is assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of management review.

Related Procedures:

Customer Related Processes	SP-720
Management Responsibility	AP-500
Planning of Product Realization Processes	MP-710

Section 6

Resource Management

6.1 Provision of resources

Cartel Electronics has implemented a Quality Management System that complies with the AS 9100 standard. This implementation was achieved with management commitment and with sufficient resources for the implementation. To effectively maintain and continually improve the system, management determines and provides necessary resources.

6.2 Human resources

6.2.1 General

To ensure competence of our personnel who perform any task directly or indirectly affecting conformity to product requirements within the quality management system, job descriptions have been prepared identifying the qualifications required for each position that affects product quality. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with required training, provide the competence required for each position.

6.2.2 Competence, awareness and training

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. Human resources maintain records of employee qualifications. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job. The results are then evaluated to determine if they were effective. Training and evaluation are conducted according to the Training procedure AP-622

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

6.3 Infrastructure

To meet quality objectives and product requirements Cartel Electronics has determined the infrastructure needed (EP-630). The infrastructure has been provided, and includes buildings, workspace, utilities, process equipment and supporting services. As new infrastructure requirements arise, they will be documented in quality plans. Existing infrastructure is maintained to ensure product conformity. Maintenance requirements are documented in:

- Preventive maintenance plans

6.4 Work Environment

A work environment suitable for achieving product conformance is maintained. Requirements are determined during quality planning and documented in the quality plan. The work environment is managed for continuing suitability. Data from the quality system is evaluated to determine if the work environment is sufficient for achieving product conformance, or if preventive or corrective action related to the work environment is required.

Related Documents

Competence, Awareness and Training	AP-622
Infrastructure	EP-630

Section 7

Product Realization

7.1 Planning of product realization

Quality planning is required before new products or processes are implemented. The quality planning takes place according to the Planning of Product Realization procedure (MP-710). During this planning, management or assigned personnel determine as appropriate:

- The quality objectives and requirements for the product, including…
  - Product and personal safety
  - Reliability, availability, and maintainability
  - Producibility, testability, and inspectability
  - Suitability of the materials used in the product
  - Needed manufacturing or quality support software
  - Compliance to environmental regulations
- Processes, documentation and resources required
- Verification, validation, monitoring, measurement, inspection and test requirements
- Criteria for product acceptance
- Resources necessary to support the use and maintenance of the product as required
- Records to provide evidence the realization process and resulting product meet requirements
- Configuration management appropriate to the product

The output of quality planning includes documented quality plans, travelers, processes, and procedures.

7.1.1 Project Management

Cartel plans and manages product realization in a structured and controlled manner to meet requirements at an acceptable risk, and within resource and schedule constraints. (See R-078 Project Management Turtle)

7.1.2 Risk Management

The process Cartel uses to determine and manage risks includes:

- Assignment of responsibilities for risk management
- Definition of risk criteria including likelihood, consequences, and acceptance or risk.
- Identification, assessment, and communication of risk throughout the manufacturing process

- Actions to be taken to mitigate or accept identified risk based upon a strategic assessment
- (See R-075 Risk Management Turtle)

7.1.3 Configuration Management:

Cartel has established, implemented, and maintains a process to manage configuration that includes as is appropriate to product…

- Configuration management planning
- Configuration identification
- Change control
- Configuration status accounting, and
- Configuration audit
- (See R-076 Configuration Management Turtle)

7.1.4 Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities

Procedure (MP-750) governs the temporary or permanent transfer of work to a location outside the Cartel Electronics home facility, and defines the process used to control and validate the quality of the work performed or supplied.

Post delivery support provides as applicable for the

- Collection and analysis of service data
- Actions to be taken, including investigation and reporting when problems are detected after delivery
- Control and updating of technical documentation
- Approval, control and use of repairs
- Controls for work conducted at the customer's site
- (See R-077 Control of Work Transfer Turtle)

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

Cartel Electronics determines customer requirements before acceptance of an order. Customer requirements include those:

- Requested by the customer
- Required for delivery and post-delivery activities

- Not stated by the customer but necessary for specified use or known and intended use
- Statutory and regulatory requirements applicable to the product
- Additional requirements determined necessary by Cartel Electronic including special requirements.

Customer requirements are determined according to the Customer Related Processes Procedure. (SP-720)

7.2.2 Review of requirements related to the product

Cartel Electronics has a process in place for the review of requirements related to the product (SP-720). The review is conducted before the order is accepted. The process ensures that:

- Product requirements are defined
- Contract or order requirements differing from those previously expressed are resolved
- Cartel Electronics has the ability to meet the defined requirements, including the identification and realization of special product requirements.
- Records are maintained showing the results of the review and any actions arising from the review
- Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance
- When product requirements are changed, Cartel Electronics communicates changes to relevant personnel and amends relevant documents
- Risks (e.g., new technology, short delivery time scale) have been evaluated.

7.2.3 Customer communication

Cartel Electronics has implemented an effective procedure (SP-720) for communicating with customers in relation to:

- Product Information
- Enquiries, contracts and order handling, including amendments
- Customer Feedback, including customer complaints

7.3 Design and Development

7.3.1 Design and Development - exclusion

Cartel Electronics manufactures bare printed circuit boards to customers' designs. Design and development processes are not applicable to Cartel Electronics.

7.4 Purchasing

7.4.1 Purchasing process

A documented procedure (AP-740*)* is followed to ensure that purchased product conforms to the specified purchase requirements. The procedure outlines the extent of control required for suppliers. Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in the procedure. Criteria for selection, evaluation and re-evaluation are documented in the procedure. Records of the evaluation and any necessary actions are maintained as quality records. Cartel Electronics is responsible for the conformity of all products purchased from suppliers, including products from customer-designated sources.

The Approved Suppliers List (F-740-003) records those suppliers approved, conditionally approved, or disapproved to supply materials or services to Cartel Electronics. Scope of supplier approvals is also defined (e.g. product type and limitations.)

Supplier performance is periodically reviewed to establish the degree of controls to be implemented, and the actions necessary for dealing with suppliers who do not meet requirements. When required, suppliers of special processes are approved by Cartel Electronics and / or Cartel's customers.

Cartel Electronics has defined the supplier approval process to include responsibility and authority for the approval decision, changes to the approval status of suppliers, and to determine and manage risks associated with the selection and use of suppliers. (See R-079 Purchasing Turtle)

7.4.2 Purchasing information

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

- Requirements for approval of product, processes and equipment
- Requirements for qualification of personnel
- Quality management system requirements outlined in the Purchasing Procedure (AP-740)
- The identification and revision status of specification, drawing, process requirements, inspections and verification instructions and other relevant technical data
- Requirements for design, test, inspection, verification (including production process verification) use of statistical techniques for product acceptance, and related instruction for acceptance for critical items and key characteristics
- Requirements for test specimens for verification or audit
- Record retention requirements
- Access to suppliers facilities and records

- Requirements for the need of the supplier to notify Cartel regarding:
  - Notify of non-conforming product
  - Approval for the shipment of non-conforming product
  - Process or material changes
  - Flow-down of Cartel requirements to the supplier's supply chain

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.

7.4.3 Verification of purchased product

The Purchasing procedure (AP-740) describes the process used to verify that purchased product meets specified purchase requirements. Purchased product is not used or processed until it has been verified as conforming to specified requirements or is released under positive recall procedure. If test reports are used to verify purchased product, the data must meet applicable specifications.

Verification activities can include:

- Obtaining objective evidence of conformity from the supplier (e.g. Certificate of Conformance, test data, statistical process control records.)
- Source inspection at the supplier's facility
- Incoming inspection

If Cartel Electronics or the customer ~~will~~ perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information. Where specified in the contract, the customer or the customer's representative is given the right to verify at the suppliers premises and organization's premises that product conforms to specified requirements. Such verification by customers does not absolve Cartel Electronics for the responsibility to provide conforming products that comply with all requirements.

7.5 Production and Service Provision

7.5.1 Control of production and service provision

Service exclusion

Cartel Electronics manufactures bare printed circuit boards to customers' designs. Service provisions are not applicable to Cartel Electronics.

Cartel Electronics plans and carries out production provision under controlled conditions according to documented procedure (MP-750). Planning considers, as applicable:

- The establishment of process controls and development of control plans where key characteristics have been identified,
- The identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization,
- The design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and
- Special processes (see 7.5.2).

Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product including drawings, parts lists, and material / process specifications
- The availability of work instructions including process flow charts, manufacturing plans, travelers, and information forms.
- The use of suitable equipment including fixtures and software
- The availability and use of monitoring and measuring devices
- The implementation of monitoring and measurement
- The implementation of product release, delivery and post-delivery activities
- Accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product), part accountability to ensure bad parts have been destroyed
- Evidence that all manufacturing and inspection verification operations have been completed as planned, or as otherwise documented and authorized
- Provision for the prevention, detection, and removal of foreign objects,
- Monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality and criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations,)
- Establishment, implementation, and maintenance of processes to manage critical items, including process controls where key characteristics have been identified,
- Designing, manufacturing, and using tooling to measure variables data

- Identification of in-process verification points, especially when adequate verification cannot be performed later
- Special processes.

7.5.1.1 Production Process Verification

Production operations are carried out in accordance with approved data. This data contains as necessary:

- Drawings, parts lists, process flow charts including inspection operations, production documents and inspection documents
- A list of specific or non-specific tools and numerical control (NC) machine programs required and specific instructions associated with their use.
- The quality system contains processes for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result to verify that the production process, documentation, and tooling are capable of producing boards that meet requirements. This process shall be 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:

Authorized people for approving changes to production processes are identified in the Procedure (MP-750). Changes affecting processes, production equipment, tools and programs are documented and procedures are available to control the implementation of changes.

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

7.5.1.3 Control of Production Equipment, Software Programs

Per procedure (MP-750), production equipment, tools and software programs used to automate, and control/monitor the product realization process are validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use includes verification of the first article produced to the design data/specification. Storage requirements, including periodic preservation/condition checks, have been established for production equipment or tooling in storage.

7.5.1.5 Control of Service Operations

Cartel Electronics manufactures bare printed circuit boards to customers' designs. Control of Service Operations does not apply.

7.5.2 Validation of special processes for production provision

Per (MP-710), Planning of Product Realization processes, Cartel Electronics validates any special processes for production provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where 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.

Cartel Electronics has documented the process for validation including:

- Defined criteria for review and approval of the processes, qualification and approval of special processes prior to use
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures,
- Control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto
- Requirements for records
- Revalidation

7.5.3 Identification and traceability

Cartel Electronics identifies the product throughout product realization according to the Identification and Traceability procedure (MP-753).

- Cartel Electronics maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.
- Product is identified with respect to monitoring and measurement requirements throughout product realization.
- When acceptance authority media such as stamps, electronic signatures or passwords are used Cartel Electronics establishes and documents controls for the media.
- According to the level of traceability required by contract, regulatory, or other established requirement, Cartel Electronics system provides for and maintains records of:
    - Identification to be maintained throughout the product life;
    - The ability to trace all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (e.g. delivery, scrap) of all products of the same batch;
    - For a given product, a sequential record of its production (manufacture, inspection / verification to be retrievable.

Cartel Electronics controls and records the unique identification of the product where ever traceability is a specified requirement

7.5.4 Customer property

Cartel Electronics exercises care with customer property while it is under the organization's control or being used. A procedure (MP-754) outlines the Identification, verification, protection and safeguarding of customer property provided for use. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained. Customer property can include intellectual property, including customer furnished data used for production and/or inspection.

7.5.5 Preservation of product

Cartel Electronics preserves the conformity of product during internal processing and delivery to the intended destination per procedure (MP-755). This preservation includes, as applicable, 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/or applicable statutory and regulatory requirement, provisions for:

- Cleaning;
- Prevention, detection and removal of foreign objects;
- Special handling for sensitive products;
- Marking and labeling including safety warnings;
- Shelf life control and stock rotation;
- Special handling for hazardous materials.

The organization ensures that documents required by the contract or order to accompany the product are present at delivery and are protected against loss and deterioration.

7.6 Control of monitoring and measuring equipment

Cartel Electronics has determined the monitoring and measurement to be undertaken and the monitoring and measuring equipment, (including but not limited to: test hardware, test software, automated test equipment, plotters used to produce inspection data, and personally owned and customer owned devices) needed to provide evidence of conformity of product to determined requirements. A documented procedure (QP-760) outlines the process used to ensure that monitoring and measurement to be carried out are carried out in a manner that is consistent with the monitoring and measurement requirements.

- 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.

- Adjusted or re-adjusted as necessary
- Identified to enable the calibration status to be determined
- Safeguarded from adjustments that would invalidate the measurement result
- Protected from damage and deterioration during handling, maintenance and storage
- Be recalled according to a defined method when requiring calibration

In addition, Quality Control assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Cartel Electronics takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained

Cartel Electronics maintains a register of these monitoring and measuring equipment. The process used for their calibration is defined in procedures, work instructions and equipment manuals and includes details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

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.

Cartel Electronics ensures that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

Related Documents

Planning of Product Realization Processes MP-710

Customer Related Processes SP-720

Purchasing AP-740

Control of Production and Service Provision MP-750

Identification and Traceability MP-753

Preservation of Product MP-755

Control of Monitoring and Measuring Devices QP-760

Section 8

Measurement, Analysis and Improvement

8.1 General

Cartel Electronics plans and implements the monitoring, measurement, analysis and improvement processes as needed

- To demonstrate conformity to product requirements
- To ensure conformity of the quality management system, and
- To continually improve the effectiveness of the quality management system.

These processes are identified in documented procedures and include determination of applicable methods, including statistical techniques, and the extent of their use.

Statistical techniques may be used to support:
- process control:
- selection and inspection of key characteristics;
- process capability measurements;
- statistical process control;
- design of experiment;
- inspection - matching sampling rate to the criticality of the product and to the process capability; and
- failure mode and effect analysis.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, Cartel Electronics monitors information relating to customer perception as to whether the organization has fulfilled customer requirements. The method for obtaining and using this information is identified in the Customer Related Processes (SP-720) and the Management Responsibility procedures (AP-500).

Information used to monitor and evaluate customer satisfaction includes:

- Product conformity
- On-time delivery
- Customer complaints
- Customer corrective action requests
- Customer satisfaction surveys
- Customer supplied performance report cards
- Lost business analysis and
- Positive feedback

Cartel has developed and implemented a process to improve customer satisfaction by addressing deficiencies identified by these evaluations, and assessing the effectiveness of the results.

8.2.2 Internal Audit

Cartel Electronics conducts internal audits at planned intervals, including to fulfill customer contract obligations as required, to determine whether the quality management system

- Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization
- Is effectively implemented and maintained.

An audit program has been designed and implemented and identifies an audit schedule based on the importance of the areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, are defined and documented in the Internal Audit procedure (QP-822).

The management responsible for the area being audited is responsible for ensuring that 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.

Records of all audit activities and correct action results are maintained.

8.2.3 Monitoring and measurement of processes

Cartel Electronics applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. Consideration is given to the type and extent of the monitoring and measuring appropriate in relation to the process' impact on product conformity and the quality management system. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product. In the event of process nonconformity, Cartel:

- Takes appropriate action to correct the nonconforming process,
- Evaluates whether the process nonconformity has resulted in product nonconformity.
- Determine if the process nonconformity is limited to a specific case or if other processes or product is affected.
- Identifies and controls any nonconforming product in accordance with clause 8.3.

The process for identifying and carrying out the required monitoring and measuring of processes is documented in the Monitoring, Measuring and Analysis of Product Realization Processes MP-824 and Management Responsibility procedures AP-500.

8.2.4 Monitoring and measurement of product

Cartel Electronics monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process identified in Monitoring, Measuring and Analysis of Product Realization Processes MP-824.

Measurement requirements for product acceptance are documented and include:

- Criteria for acceptance and / or rejection
- Where in the sequence measurement and testing operations are performed
- Required records of measurement results (at a minimum indications of acceptance or rejection,) and
- Any specific measuring instruments required and any specific instructions associated with their use.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of product for delivery to the customer and provide evidence that the product meets the defined requirements. Product release and service delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

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

Product is not used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities. Product that has not been inspected or verified as conforming is identified to allow for the recall and replacement in the event it is subsequently found to not meet requirements.

Sampling plans, when used, are based on recognized statistical principals, and match the criticality of the product characteristic being verified to the capability of the process producing the item being evaluated.

Unless approved by Cartel Management or the customer where applicable, product is not released to the customer until all planned arrangements have been satisfactorily completed.

Procedures are in place to ensure that all documents required to accompany product are present at the time of delivery.

8.3 Control of Nonconforming Product

Cartel Electronics ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in the Control of Nonconforming Product procedure (QP-830).

The term “nonconforming product” includes nonconforming product returned from a customer.

Responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions is defined in the procedure.

Cartel Electronics does not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if

- The product is produced to customer design, or
- The nonconformity results in a departure from the contract requirements.

Where applicable, Cartel Electronics deals with non-conforming product in one of the following ways:

- By taking action to eliminate the detected non-conformity
- By taking appropriate action to preclude its original intended use or application including after delivery. Any instance or non-conformity is promptly reported to customer upon discovery.
- By taking the necessary actions to contain the effect of the non-conformity on other processes or products.

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

In addition to any contract or regulatory authority reporting requirements, Cartel Electronics system provides for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification includes a clear description of the nonconformity, which includes as necessary parts affected, customer and/or organization part numbers, quantity, and date(s) delivered.

Parties requiring notification of nonconforming product may include suppliers, internal departments, customers, distributors, and regulatory authorities.

8.4 Analysis of Data

Cartel Electronics determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. The process for determining, collecting and analyzing this data is defined in the Statistical Techniques procedure (QP-840). Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

- Customer satisfaction
- Conformance to product requirements
- Characteristics and trends of processes and products including opportunities for preventive action
- Suppliers

8.5 Improvement

8.5.1 Continual improvement

Cartel Electronics 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. Implementation of improvement activities, which may include lessons learned, problem resolutions, or benchmark of best practices, are then evaluated for the effectiveness of the results.

8.5.2 Corrective action

Cartel Electronics takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure (QP-852) defines requirements for

- Reviewing nonconformities (including customer complaints),
- Determining the causes of nonconformities,
- Evaluating the need for action to ensure that nonconformities do not recur,
- Determining and implementing action needed,
- Records of the results of action taken (see 4.2.4), and
- Reviewing the effectiveness of corrective action taken.
- Flowing down of the corrective action requirements to a supplier, when it is determined that the supplier is responsible for the root cause,
- Specific actions where timely and/or effective corrective actions are not achieved and,
- Determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action as required.

8.5.3 Preventive action

Cartel Electronics 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 (QP-852) defines requirements for:

- Determining potential nonconformities and their causes
- Evaluating the need for action to prevent occurrence of nonconformities
- Determining and implementing action needed
- Records of results of action taken
- Reviewing the effectiveness of preventive action taken

Preventive actions may include:

- Risk management
- Error Proofing
- Failure mode and effect analysis
- Actions based on information reported by external sources

Related Documents

Management Responsibility AP-500

Customer Related Processes SP-720

Monitoring, Measuring and Analysis of Customer Satisfaction AP-821

Internal Audits QP-822

Monitoring and Measuring of Product and Realization Processes MP-824

Control of Nonconforming Product QP-830

Corrective Action QP-852

Preventive Action QP-852

Statistical Techniques QP-840