



Central Electropolishing Co.
Quality System Manual and Procedures
ISO 9001
AS9100b
ISO 13485

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CELCO Quality Manual and Procedures Revision Notes

Revision Level	Change Description	Date
Original	Original Release	7-19-01
REV A	Clarification; addition of forms	12-30-01
REV B	Clarification of manual.	1-11-07
REV C	Modify entire quality manual to meet ISO 9001, AS9100b and ISO 13485	5-14-07
REV D	Deleted Process Parameters for Medical Device Sterilization, and Shelf Life Records, changed checking Iron Content every 90 Days to As Needed. Added Process Numbers	8-04-08
REV E	Added Risk Management to Records of (Identification) para.4.2.4 Added tolerance and approval for use to para. 6.3 Added persons approved to make processes changes to para. 7.5.1.2 Added Inspection stamps will not be re-issued for 6 months after termination of employee to para. 7.5.3	10/22/08
REV F	Changed – all micrometers will be calibrated and certified semi-annually to; all micrometers will be calibrated and certified biennially in para. 7.6 (f)	9/22/09
REV G	Storage Times for Medical History Sheets added to para. 4.2.4 Quality Objectives changed in para. 5.4.1	3/15/10

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1.0 CELCO MISSION STATEMENT/QUALITY STATEMENT

Celco will comply with requirements and work to continually improve the effectiveness of the quality management system.

We will strive to supply the highest quality service from our employees and subcontractors at competitive prices in the most expeditious manner possible. We will provide safe working conditions for our employees and our environment.

We will strive to meet or exceed our customer’s expectations while improving our operations, facility and techniques to keep up with the ever changing world of Metal Finishing Services.

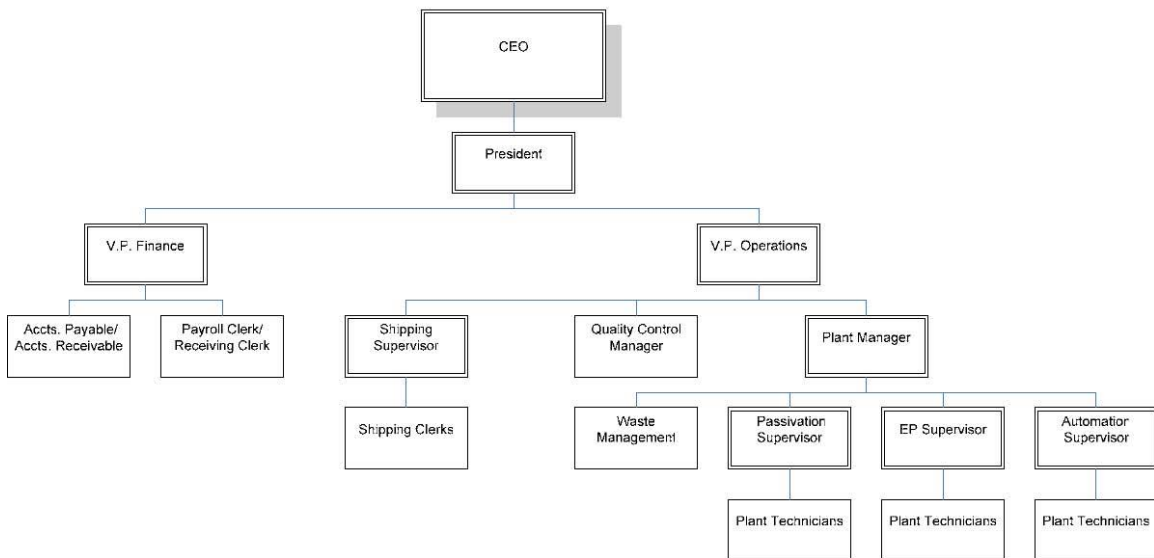
2.0 SCOPE

This manual is written to afford the responsibility of Central Electropolishing Co., Inc. also referred to as CELCO, to establish a Quality Control Program for inspections and examinations necessary to meet the needs of our clients and uphold the required compliance to the appropriate specifications and drawing instructions of the same clients.

The enclosed organizational chart divides the company’s responsibility to separate the Quality Control System from the other operations, but does not remove the responsibility of each sections to monitor and perform the inspections necessary to be in compliance with the customers requirements.

It will be the responsibility of the supervisory personnel to work with the Quality Control Manager and maintain the quality standards.

Central Electropolishing Co., Inc.
Organizational Chart



3.0 QUALITY CONTROL DEPARTMENT

The Quality Control Manager has the responsibility of developing and implementing a Quality Control System to insure that necessary compliance of customer instructions is honored. The Quality Control Managers' duties will include, but not limited to:

- Develop and maintain a Quality Control Manual.
- Supervise the implementation of a Quality Control System.
- Provide instructions for the development of internal quality procedures.
- Review that all material received is in accord with the purchase order and/or the quotation.
- Assure that the traveling work order is proper and stating all information for production.
- Maintain all Quality Control records. QC Manager will sign and date all Work History Sheets. All customer complaints require the QC Manager to fill out Form G to show corrective action. QC Manager will maintain an Electronic copy of all Work History Sheets in their computer.
- Delegate duties to other designees to act in the QC Managers behalf for quality inspections.

4. QUALITY MANAGEMENT SYSTEM:

4.1 General Requirements:

CELCO has established, documented, implemented and maintains a quality management system and strives to continually improve the quality systems effectiveness in accordance with the requirements of ISO 9001, AS9100b and ISO 13485

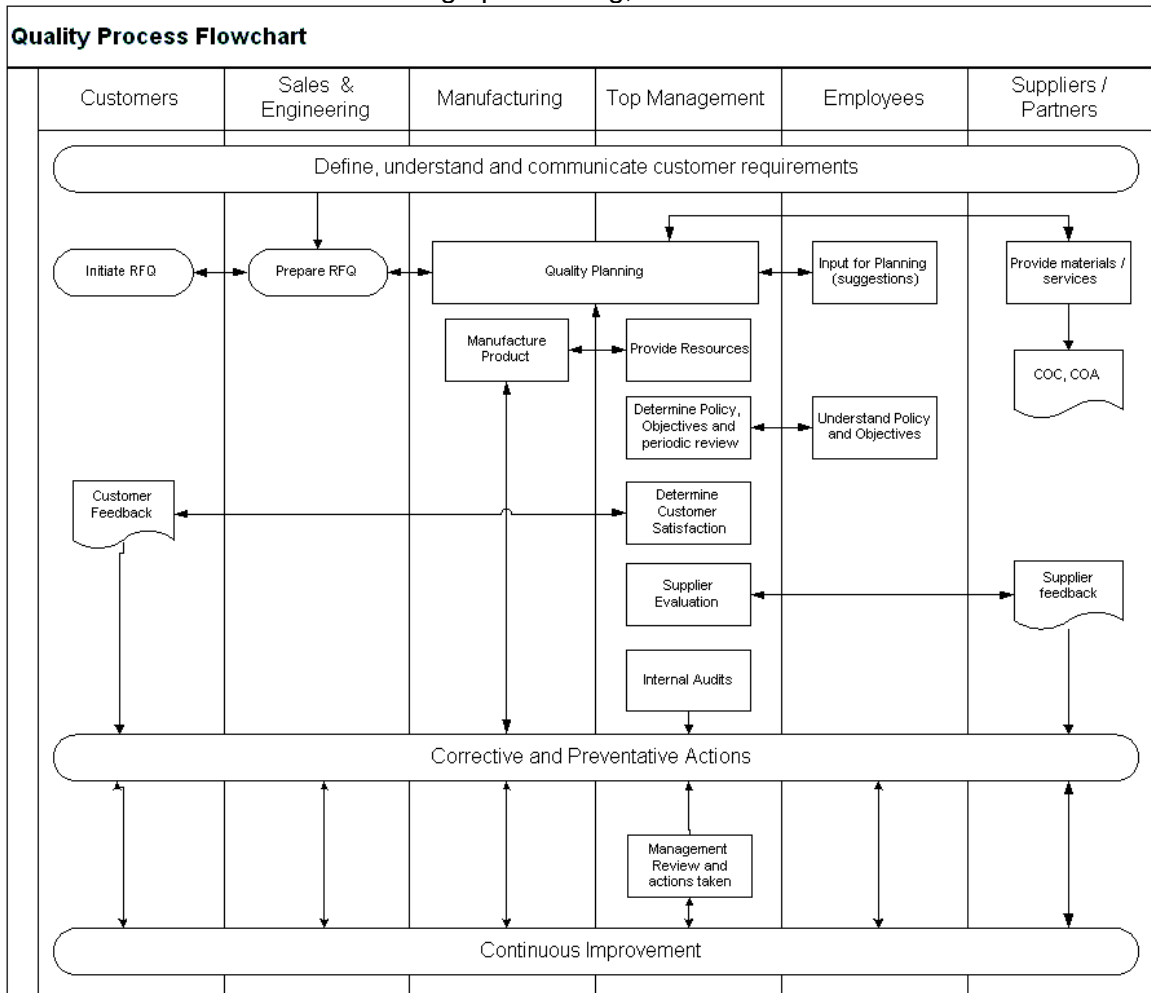
CELCO has identified the processes needed for the quality management system and the application of needed processes throughout the organization. Flowcharts have been prepared to show the sequence and interaction of these processes. CELCO has determined methods to be used for operation and control of these processes and has determined the criteria needed.

Top management uses input from personnel, quality results, and management review to ensure the availability of appropriate resources and information necessary to support the operation and monitoring of these processes.

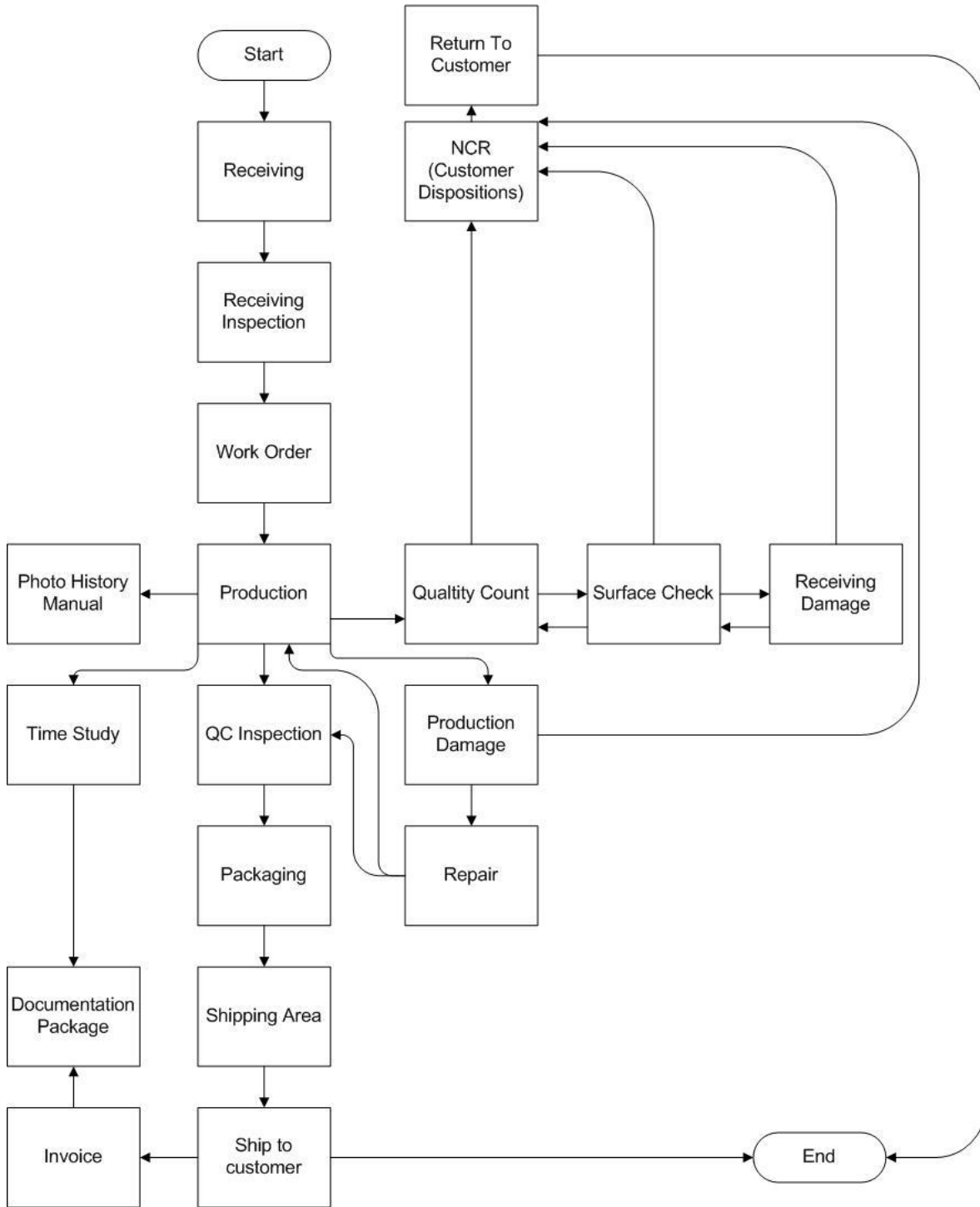
Processes are monitored, measured and analyzed to provide a baseline for data and metrics for continual improvement. Flowcharts are found on the pages following.

CELCO implements actions necessary to achieve planned results and maintain the effectiveness of these processes.

CELCO control subcontracted services through purchasing, see 7.4.



CELCO – Production Flowchart



4.2 Documentation Requirements:

4.2.1 The quality management system documentation of CELCO contains all documentation required by: ISO 9001, AS9100b and ISO 13485 as well as quality related documentation required by customers.

This manual provides for:

- a. documented statements of a mission statement/quality policy and reference to quality objectives,
- b. a quality manual,
- c. documented procedures required: (by inclusion or reference),
- d. documents needed by CELCO to ensure the effective planning, operation and control of its processes,
- e. records required (see 4.2.4)
- f) *any other documentation specified by national or regional regulations.*

Where this International Standard specifies that a requirement, procedure, activity or special arrangement be “documented”, it shall, in addition, be implemented and maintained.

For each type or model of medical device, CELCO shall establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirements (see 4.2.3). These documents shall define the complete manufacturing process and, if applicable, installation and servicing.

CELCO ensures that personnel have access to quality management system documentation and are aware of relevant procedures. Customers and/or regulatory authorities or their representatives have access to agreed portions of the quality management system documentation and records.

4.2.2 The CELCO Quality Manual

The scope of this quality management system covers Electropolishing, Passivation and Precision Cleaning. CELCO also provides some assembly.

This manual has been developed to administer procedures for the control of quality and continuous improvement efforts to ensure customer satisfaction for our products and services.

CELCO excludes design 7.3 and servicing provisions of 7.5.1 and 7.5.2. This is justified by the fact that CELCO provides a service that meets customer requirements.

This manual contains all required procedures or a reference to procedures and they are organized by the general clause numbers provided by AS9100b in order to show their relationship. Referenced procedures are made from the section of the manual corresponding the top level numbered clauses of the standard.

The table of contents in this manual outlines the structure of the documentation used in the Quality Management System

A description of the interaction between the processes of the quality management system is shown on the flowcharts.

4.2.3 CONTROL OF DOCUMENTS PROCEDURE

Documents required by the quality management system are controlled. The procedure for control is as follows. Each document *is approved for adequacy prior to issue*, reviewed and updated and re-approved as needed by the VP OPERATIONS. Controlled copies of this manual are available online to indicate that they are controlled. Revision notes are kept for CELCO procedures to ensure that changes are known. The VP OPERATIONS also ensures that documents remain legible and readily identifiable and that relevant versions of applicable documents are available at points of use.

Documents of external origin are identified and their distribution is controlled. Examples of these types of documents may include: ISO 13485 and AS9100b standards, customer supplied data.

A history file of closed purchase orders is maintained for reference.

The VP OPERATIONS or authorized designee shall prevent the unintended use of obsolete documents and apply suitable identification to them if they are retained for any purpose.

Where required by customer contracts or regulatory authority, the VP OPERATIONS or authorized designee coordinates any needed document changes.

Where applicable, for medical devices, CELCO shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function which has access to pertinent background information upon which to base its decisions.

Where applicable, for medical devices, CELCO shall define the period for which at least one copy of obsolete controlled documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.4), or as specified by relevant regulatory requirements.

4.2.4 CONTROL OF RECORDS PROCEDURE

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records are to remain legible, readily identifiable and retrievable. The procedure defining the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records is shown below. The procedure for control includes records that are created by suppliers if applicable, as well as those required by customer contract. At CELCO, shredding destroys all records. The function named as responsible is responsible for ensuring that records are created, maintained and made available in accordance with the table below.

For medical devices, CELCO shall retain the records for a period of time at least equivalent to the lifetime of the medical device as defined by the CELCO, but not less than two years from the date of product release by CELCO or as specified by relevant regulatory requirements. Obsolete History Sheets for Medical Devices shall be stored indefinitely on computer and storage disc.

Records of (identification)	Location	Reference	Responsibility	Time (minimum)
Management reviews	Office	5.6.1	President	2 yrs
Training records	Office	6.2.2	VP Operations	2
Maintenance Records	Office	6.3	VP Operations	2
Planning of Product (Job Traveler)(Work Order)(History Sheet, including Medical)	Office	7.1	VP Operations	7
Quote reviews	Office	7.2.2	VP Operations	6 months
Contract reviews	Office	7.2.2	VP Operations	7
Purchasing Records (ID & Traceability to the extent required)	Office	7.4	VP Operations	7
Purchasing records of verification	Office	7.4	VP Operations	7
Supplier Evaluations and actions arising from the evaluation	Office	7.4	VP Operations	2
Risk Management	Office	7.1	VP Operations	7
Special Process records (Electropolish, Passivate, O2 Cleaning)	Office	7.5.2	VP Operations	7
Inspection and test records (in process)	Office	7.5.3	VP Operations	7
Inspection and test records (final)(release of product)	Office	8.2.4	VP Operations	7
Customer Property (if damaged)	Office	7.5.4	VP Operations	2
Calibration records (monitoring, measuring equipment)	Office	7.6	VP Operations	7
Internal audit results	Office	8.2.2	VP Operations	7
Implantable medical devices- identity of inspection personnel	Office	8.2.4.2	VP Operations	7
Nonconforming product and disposition (including waivers & concessions, if made)	Office	8.3	VP Operations	7
Medical – identity of persons making concessions	Office	8.3	VP Operations	7
Analysis of data records	Office	8.4	VP Operations	7
Corrective & Preventive actions including customer complaints, root cause investigations and follow-up	Office	8.5.2 & 8.5.3	VP Operations	7

4.3 Configuration Management

Configuration management at CELCO is managed in accordance with customer requirements. Customers of CELCO specify product requirements and communicate those requirements via suitable means.

5. MANAGEMENT RESPONSIBILITY:

5.1 Management Commitment:

Top management has provided evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- a. Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, at CELCO staff briefings and employee meetings covering these issues.
- b. establishing the Mission Statement/Quality Policy as follows:
Celco will comply with requirements and work to continually improve the effectiveness of the quality management system
We will strive to supply the highest quality service from our employees and subcontractors at competitive prices in the most expeditious manner possible. We will provide safe working conditions for our employees and our environment.
We will strive to meet or exceed our customer's expectations while improving our operations, facility and techniques to keep up with the ever changing world of Metal Finishing Services.
- c. CELCO quality objectives are established and reviewed in the top management review of the quality system and its performance. These objectives may be changed from time to time and are reflected in the minutes of the management review meeting. Where ever possible, metrics are employed to chart our progress in meeting the quality objectives.
- d. Management reviews are conducted covering applicable quality issues at least semi-annually. Minutes of the meeting are used to record required information. (Reference ¶ 5.6)
- e. Availability of adequate quality system resources will be included in management reviews of the quality system and in staff meetings as appropriate.

5.2 Customer Focus:

Top management ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

5.3 Mission Statement/Quality Policy:

Top management has ensured that the mission statement/quality policy (reference ¶ 5.1b) is appropriate to the purpose of the organization and includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system. Top management also has provided a framework for establishing and reviewing quality objectives in the management review meetings. Top management has ensured that the quality policy and objectives are communicated and understood within the organization.

At least semi-annually at the management review meeting, the quality policy, this document and quality objectives are reviewed for continuing suitability.

5.4 Planning:

5.4.1 Quality Objectives:

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

The Quality Objectives are as follows:

- 1) Reduce Customer Complaints
- 2) Reduce Non-Conformance Reports

5.4.2 Quality Management System Planning:

Top management shall ensure that the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives. When changes to the quality management system are anticipated, management will plan the implementation of the change so that the integrity of the quality system is maintained.

5.5 Responsibility, Authority and Communication:

5.5.1 Responsibility and Authority:

Top management has ensured that the responsibilities and authorities are defined, **documented** and communicated within the organization. See organizational chart in section 1.0 of this manual.

Top management has established the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.

5.5.2 Quality Management Representative:

The VP OPERATIONS at CELCO serves as the Quality Management Representative (QMR). In addition to any other responsibilities, the VP OPERATIONS has the responsibility and authority to:

- a. ensure that processes needed for the quality management system are established, implemented and maintained,
- b. report to management on the performance of the quality management system and any needs for improvement,
- c. ensure the promotion of awareness of **regulatory** and customer requirements throughout the organization, and
- d. the freedom to resolve matters pertaining to quality.

5.5.3 Internal Communication:

Top management has ensured that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. CELCO accomplishes this by periodic employee briefings and quality information displayed at time clocks regarding Mission Statement and quality objectives.

5.6 Management Review:

5.6.1 General:

Top management shall review the quality management system at least semi-annually. This review is conducted to ensure its continuing suitability, adequacy and effectiveness as well as assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Minutes kept provide the records from management reviews.

5.6.2 Review Input:

The input to management review includes information on

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

5.6.3 Review Output:

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

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

6. RESOURCE MANAGEMENT:

6.1 Provision of Resources:

CELCO determines and provides the resources needed to implement and maintain the quality management system and continually improve **and maintain** its effectiveness. Management ensures that resources are available to enhance customer satisfaction by meeting customer requirements and *to meet regulatory and customer requirements*.

6.2 Human Resources:

6.2.1 Management ensures that personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience. These requirements are supported by education and training records.

6.2.2 Competence, Awareness and Training:

CELCO determines the necessary competence for personnel performing work affecting product quality as described above and then provides training or takes other actions to satisfy these needs. Observation of demonstrated ability is used to evaluate the effectiveness of the training and actions taken. This process ensures that CELCO personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives. Appropriate records of education, training, skills and experience are maintained.

6.3 Infrastructure:

Management at CELCO determines the need for infrastructure resources to achieve conformity to product requirements. These resource needs are obtained through staff meetings and the review of the quality management system. Items considered in staff meetings and management reviews are buildings, workspace and associated utilities, processing equipment and supporting services as appropriate.

CELCO has established documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality. Records of such maintenance shall be maintained (see 4.2.4).

Maintenance Records:

All electrolyte fluids used in Electropolish processes will be checked and recorded for specific gravity and temperature balance at least twice weekly (Form D). The iron level of the electrolyte of each tank will be checked when a change in the performance of the fluid is noticed that is not contributed to specific gravity or temperature. These records will be filed in the Quality Control Managers office. The balance of specific gravity will be controlled by adding water to lower the specific gravity and boiling out the water to raise the specific gravity. A maintenance record with the above information will be kept in the supervisor's office. All complete forms will be kept in the QC Managers office.

6.4 Work Environment:

CELCO provides the work environment needed to achieve conformity to product requirements. This may include control of temperature, humidity, lighting and cleanliness. Quality system audits may provide feedback to management on work environment issues.

The following requirements shall apply.

a) CELCO has established documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product (see 7.5.1.2.1).

b) If work environment conditions can have an adverse effect on product quality, CELCO has established documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions (see 7.5.1.2.1).

c) CELCO has ensured that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person [see 6.2.2 b)].

d) If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel (see 7.5.3.1).

TRAINING PROGRAMS AT CELCO

Safety Orientation and Training

CELCO employees prior to starting on the job training will complete some or all of the Safety Programs and be tested on these same programs. Some employees are required to take additional training because of work that they may be required to perform. Employees completing the required safety orientation will sign off on each test sheet completed.

Safety Programs are as follows:

Respiratory Protection: Employees will learn about respiratory hazards and how to protect themselves against them. They will learn about the 4 different types of respirators used in our operation such as the dust mask, cartridge, air supplied and SCBA (used only in emergency situations). In addition, employees will be fit tested using a qualitative and quantitative fit test to OSHA guidelines and supplied with the proper equipment for their particular project.

Hazard Communication: Employees will learn how to read a MSDS, so that they can protect themselves against exposure to harmful chemicals. Included are some brief scenarios of situations they may encounter while on the job at CELCO.

Lockout/Tagout: Personnel will be instructed in the use of Lockout/Tagout equipment in a variety of situations. They will learn to take the possibility of an accident out of the equation by eliminating any power or energy source and the correct protocol to implement a successful Lockout/Tagout program.

Forklift Safety: Personnel selected to be Forklift operators are required to complete this section and test along with an actual obstacle course evaluation before performing duties as an operator. Individuals will learn about overall safety and accident prevention covering the use of the Forklifts.

Confined Space Entry: Individuals working in enclosed areas are required to take this section concerning vessel and confined space entry. Personnel will learn about individual responsibilities concerning entry and protocol concerning this activity. Examples of hazards and how to prevent them are illustrated in this section.

Operator Training/On the Job Training/Documentation

Because of the nature of the work performed at CELCO, it is necessary to instruct employees as they perform their duties (on the job training). Typically, new hires are started on simple tasks such as pin racked parts and advanced to more difficult projects as they become more experienced. New hires are subject to a 90 day probation period during which their employment can be terminated without explanation. Generally there would be an explanation because either the employee failed to grasp CELCO's techniques in Metal Finishing or because employee failed to comply with rules and guidelines spelled out in the CELCO Employee Handbook. Upon successful completion of the probationary period they will become regular (full-time) employees. The employee will learn to follow particular procedures on a variety of products, many which are governed by specifications determined by our clients. Employee will fill out and initial their portion of the Part(s) Traveler on each step completed. Following completion of their project the employee will fill out, date and initial the Time Study attached to each work order that accompanies every job they do. These Time Studies are used to evaluate not only prices, but also to document efficiency of each employee to perform quality work at the particular task. (Documentation of Performance Time Studies.) The time study serves as one method used by Celco to document employee training.

7. PRODUCT REALIZATION:

7.1 Planning of Product Realization:

CELCO has developed plans for processes needed for processing of product. Planning of product realization is provided on the job traveler and its referenced documents. This method of producing product planning is consistent with the requirements of the other processes of the quality management system. CELCO plans product realization taking into account the following items as appropriate:

- a. quality objectives and requirements for the product;
- b. the need to establish processes, documents, and provide resources specific to the product;
- c. required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance
- d. records needed to provide evidence that the manufacturing processes and resulting product meet requirements (see 4.2.4);
- f. the identification of resources to support production.

g. CELCO has evaluated the Risks associated with all known aspects of product realization and will review Risks in management meetings to re-evaluate.

7.2 Customer-Related Processes:

7.2.1 Determination of Requirements Related to the Product:

CELCO has determined product requirements specified by the customer, including the requirements for delivery. CELCO does not provide post-delivery activities. Where the customer does not state requirements, but they are found necessary for the specified or intended use, CELCO determine these requirements. CELCO also makes known and translates into requirements any statutory and regulatory requirements related to the product as well as any additional requirements determined by CELCO.

7.2.2 Review of Requirements Related to the Product:

CELCO reviews requirements related to the product. This review shall be conducted prior to CELCO's commitment to supply a product to the customer. All quotations, contracts and orders, including changes made, are reviewed to ensure that:

- a. product requirements are defined **and documented**,
- b. any contract or order requirements differing from those previously expressed are resolved,
- c. CELCO has the ability to meet the defined requirements,
- d. Risks, due to new technology, new processes or short delivery times are evaluated.

Records of the results of the review and actions arising from the review are maintained as quality records.

CELCO accepts purchase orders or requests for quotations. If product requirements are changed, CELCO ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Customer Communication:

CELCO determines and implements effective arrangements for communicating with customers in relation to product information, inquiries, contracts or orders including amendments. CELCO communicates with customers and effectively handles customer complaints.

CELCO has excluded the process of determining and implementing effective arrangements for communicating with customers in relation to advisory notices because this requirement is outside the scope of CELCO's quality management system.

7.3 Design and Development

(Excluded with justification: CELCO provides service to customer specifications)

7.4 Purchasing:

7.4.1 Purchasing Process:

PURCHASING PROCEDURE

CELCO ensures that purchased product conforms to specified requirements. The type and extent of control applied to the supplier and the purchased product, is dependent upon the effect of the purchased product on the quality of our product.

CELCO is responsible for the quality of all products purchased from suppliers, including any customer-designated sources.

CELCO evaluates and selects suppliers based on their ability to supply product in accordance with the stated requirements.

Suppliers are Re-evaluated by CELCO at least annually, based on the performance of the supplier. Records of the results of evaluations and any necessary corrective actions arising from evaluations are maintained as quality records.

CELCO maintains a list of approved suppliers that includes the scope of their approval. Suppliers to CELCO are reviewed (re-evaluated) for performance as noted above. The results of these reviews are used as a factor in establishing the level of controls to be implemented. When suppliers do not meet requirements, a corrective action request will be issued to the supplier. Any supplier that fails to satisfactorily complete a corrective action request may be removed from the approved supplier's list.

CELCO ensures that where required, CELCO and all suppliers use customer-approved special process sources.

The President working with the Management Team has the responsibility for approving supplier quality systems and has the authority to disapprove the use of sources.

7.4.2 Purchasing Information:

Purchase orders or referenced attachments describe the product to be purchased, including **where appropriate:**

- a. requirements for approval of product, procedures, processes and equipment,
- b. requirements for qualification of personnel,
- c. quality management system requirements,
- d. the name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data,
- e. requirements for design, test, examination, inspection and related instructions for acceptance by CELCO,
- f. requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing,
- g. requirements relative to supplier notification of nonconforming product and arrangements for the CELCO approval of supplier nonconforming material,
- h. requirements for the supplier to notify CELCO of changes in product and/or process definition and, where required, obtain CELCO approval,
- i. right of access by CELCO, the customer of CELCO, and regulatory authorities to all facilities involved in the order and to all applicable records, and
- j. requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.

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

To the extent required for traceability given in 7.5.3.2, CELCO shall maintain relevant purchasing information, i.e. documents (see 4.2.3) and records (see 4.2.4).

7.4.3 Verification of Purchased Materials/Service:

CELCO has established and implemented inspection or other activities necessary to ensure that purchased product meets specified purchase requirements.

CELCO verification activities may include ***as applicable***:

- a. obtaining objective evidence of the quality of the product from suppliers including: accompanying documentation, certificate of conformity, test reports, statistical records, and process control records,
- b. inspection and audit at supplier's premises,
- c. review of the required documentation, and
- d. inspection of materials upon receipt.

Records of the verification shall be maintained (see 4.2.4)

Purchased materials are verified as conforming by utilizing visual means and subsequent tests during processing. Purchased services are verified as conforming by visual and other means.

Where CELCO utilizes test reports to verify purchased material/service, the data in those reports must be acceptable per applicable specifications.

CELCO periodically validates test reports on raw material.

CELCO does not delegate verification activities to a supplier.

Where CELCO or the customer of CELCO intends to perform verification at the supplier's premises, these verification arrangements and the method of product release is contained in the purchasing information. Where specified in the contract, the customer or the customer's representative shall be afforded the right to verify at the supplier's premises and CELCO's premises that subcontracted product conforms to specified requirements.

Verification by the customer is not used by CELCO as evidence of effective control of quality by the supplier and shall not absolve CELCO of the responsibility to provide acceptable product, nor does it preclude subsequent rejection by the customer.

7.5 Production and Service Provision:

7.5.1 Control of Production and Service Provision:

CELCO considers the following when planning the processing of product, ***where 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
- the qualification of operators or monitoring of special processes, where results cannot be confirmed by direct inspection or test.

CELCO plans and carries out processing in accordance with the applicable procedures and operations in sequence on the job traveler.

Processing controlled conditions include, as ***applicable the***:

- a) availability of information that describes the characteristics of the product,
- b) [the availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary,](#)

- c) use of suitable equipment,
- d) availability and use of monitoring and measuring devices as needed,
- e) implementation of monitoring and measurement as required by the product,
- f) implementation of release and delivery of products,
- g) accountability for all product during processing (e.g., part quantities, split orders, and nonconforming product),
- h) evidence that all processing and inspection operations have been completed as planned, or as otherwise documented and authorized,
- i) provision for the prevention, detection, and removal of foreign objects,
- j) monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality, and
- k) criteria for workmanship, which is described in written standards, representative samples or illustrations.
- l) **the implementation of defined operations for labeling and packaging. CELCO shall establish and maintain a record (see 4.2.4) for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the amount manufactured and amount approved for distribution. The batch record shall be verified and approved. A batch can be a single medical device.**

7.5.1.1 Production Documentation:

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

- a) drawings, parts lists, process flow charts including inspection operations, production documents, including the job traveler and it's references and inspection documents and
- b) a list of specific or non-specific tools and/or computer programs required and any specific instructions associated with their use.

7.5.1.2 CONTROL OF PRODUCTION PROCESS CHANGES PROCEDURE:

Processes at CELCO are performed in accordance with CELCO Processing Procedures such as:

- Electropolish 1000
- O2 Cleaning 1011
- Passivation 1005
- Aqueous Cleaning 1021

And/or prescribed customer specifications.

Persons authorized to approve changes to production processes are the Production Manager, VP of Operations, Quality Manager, President, or CEO.

7.5.1.2.1 Cleanliness of product and contamination control

CELCO does not provide sterilization processing services.

7.5.1.2.2 Installation activities

CELCO does not perform any medical device installation.

7.5.1.2.3 Servicing activities for Medical Devices

CELCO does not provide repair and maintenance.

7.5.1.3 AEROSPACE: Control of Production Equipment, Tools and Computer Programs: PROCEDURE

Production equipment, tools and computer programs (affecting processes) shall be validated prior to first use and maintained and re-validated periodically. Validation prior to production use includes verification of the first article produced to the specification.

7.5.1.3 MEDICAL: Particular requirements for sterile medical devices

CELCO does not provide sterilization processing services.

7.5.1.4 Control of work transferred, on a temporary basis, outside of the CELCO facility:

CELCO does not transfer work on a temporary basis outside of the facility.

7.5.1.5 Control of Service Operations:

CELCO does not provide service operations.

7.5.2 Validation of Processes for Production and Service Provision (Special Processes):

Validation of Processes for Production and Service Provision: CELCO shall validate any processes for production and service 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 shall demonstrate the ability of these processes to achieve planned results.

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

- a. defined criteria for review and approval of the processes, for example the qualification and approval of special processes prior to use,
- b. approval of equipment and qualification of personnel,
- c. use of specific methods and procedures, for example the control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto,
- d. requirements for records (see 4.2.4), and
- e. revalidation.
- f. tests required by the processing specification.

CELCO does not utilize computer software to validate product.

CELCO currently performs the following special processes in the facility.

- Electropolishing – Celco 1000
- Passivation – Celco 1005
- O2 Cleaning – Celco 1011
- Aqueous Cleaning – Celco 1021

7.5.2.2 Particular requirements for sterile medical devices

CELCO does not provide sterilization processing services.

7.5.3 Identification and Traceability:

The procedure for Traceability is as follows:

Where appropriate, CELCO shall identify the product by suitable means throughout product realization and shall establish documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required. History Sheets for Medical Devices will be maintained for 7 years. Obsolete History Sheets will be stored indefinitely on computer and storage disc in a separate folder.

At CELCO the process traveler is utilized to provide for product traceability.

CELCO shall establish documented procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product [see 6.4 d)].

CELCO shall maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

CELCO shall identify the product status with respect to monitoring and measurement requirements.

When acceptance authority media are used (e.g., stamps and/or initials), CELCO shall establish and document controls for the media.

Where traceability is a requirement, CELCO shall control and record the unique identification of the product (see 4.2.4).

According to the level of traceability required by contract, regulatory, or other established requirement, CELCO's system shall provide for:

- a. identification to be maintained throughout the product life;
- b. batch control where required,
- c. for an assembly, the identity and traceability of its components (O2 Cleaning)
- d. where applicable, for a given product, a sequential record of its production can be retrieved (History Sheets)

STAMP/INITIALS CONTROL PROCEDURE

Stamps/initials are used to mark materials and paperwork to indicate acceptance by qualified personnel. A list of personnel with their assigned stamp/initials is maintained by VP Operations. Assigned inspection stamps will not be re-assigned for 6 months after termination of employment.

7.5.3.2 Traceability

7.5.3.2.1 General

CELCO has established documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required (see 4.2.4, 8.3 and 8.5). See above.

7.5.3.2.2 Particular requirements for active implantable medical devices and implantable medical devices

In defining the records required for traceability, CELCO includes records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements.

CELCO provides processing services for the customer and does not deliver finished product to agents or distributors.

Records of the name and address of the shipping package consignee shall be maintained (see 4.2.4).

7.5.3.3 Status identification

The identification of product status shall be maintained throughout processing and storage of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed.

7.5.4 Customer Property:

CELCO exercises care with customer property while it is under our control. CELCO identifies, verifies, protects and safeguards customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, it will be reported to the customer and quality records will be maintained. Customer property can include intellectual property, including customer-furnished data used for design, production and/or inspection. **It can also include confidential health information.**

7.5.5 Preservation of Product PROCEDURE:

CELCO does not have any product that has a limited shelf life or special storage conditions. CELCO does store products in accordance with customer requirements.

CELCO preserves the conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection. Preservation also applies (if appropriate) to the component parts of a product. Preservation of product includes, where applicable in accordance with product specifications and/or applicable regulations, provisions for:

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

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

7.6 Control of Monitoring and Measuring Devices PROCEDURE:

CELCO determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to specified requirements.

CELCO maintains a list of measuring devices that defines the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria. The list of devices includes as applicable, test hardware, test software, automated test equipment used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.

CELCO uses processes to ensure that monitoring and measurement can be carried out in a manner that is consistent with the measurement requirements. Additionally, CELCO ensures that environmental conditions are suitable for the calibrations, inspections, measurements and tests being performed.

Where necessary to ensure valid results, measuring equipment is:

- a) calibrated or verified at specified intervals on the list, or prior to use, against measurement standards traceable to international or national measurement standards; if no such standards exist, the basis used for calibration or verification shall be recorded;
- b) adjusted or re-adjusted as necessary;
- c) identified to enable the calibration status to be determined;
- d) safeguarded from adjustments that would invalidate the measurement result;

- e) protected from damage and deterioration during handling, maintenance and storage;
- f) VP OPERATIONS monitors due dates of measuring devices as appropriate.

In addition, the quality function assesses and records the validity of the previous measuring results if the equipment is found not to conform to requirements. CELCO will take appropriate action for the equipment and any product affected. Records of the results of calibration and verifications are maintained as quality records. If used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This is undertaken prior to initial use and reconfirmed as necessary.

Instrument Calibration and Documentation:

The profilometer measurement pads will be certified annually to the pads' original reading. All micrometers will be calibrated and certified biennially or when deemed necessary because of potential damage. The calibration table (Form E) will be completed denoting the instrument, item description, date of calibration, method, standards, quality control initial, results and calibration due date. The hydrometer, thermometer and other Certifications will be filed with the Calibration Table. These certifications will be filed in the Quality Control Managers office.

8. MEASUREMENT, ANALYSIS AND IMPROVEMENT:

8.1 General:

CELCO plans and implements the monitoring, measurement, analysis and improvement processes required to:

- a) demonstrate conformity of the product,
- b) ensure conformity of the quality management system, and
- c) continually improve and [maintain](#) the effectiveness of the quality management system.

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

8.2 Monitoring and Measurement:

8.2.1 Customer Satisfaction:

CUSTOMER SATISFACTION PROCEDURE

As one of the measurements of the performance of the quality management system, CELCO monitors information relating to customer perception as to whether or not we have met customer requirements. CELCO may use a questionnaire that may be administered by phone, mail or e-mail to obtain this information.

This procedure for a feedback system [see 7.2.3] is to provide early warning of quality problems and for input into the corrective and preventive action processes (see 8.5.2 and 8.5.3).

If national or regional regulations require CELCO to gain experience from the post-production phase, the review of this experience shall form part of the feedback system (see 8.5.1).

8.2.2 INTERNAL AUDIT PROCEDURE:

CELCO conducts internal audits in accordance with the internal audit schedule to determine whether the quality management system is conforming to the planned arrangements. This includes a review of conformance to the requirements AS9100b ISO 13485 and this manual. The purpose of the audit is to demonstrate that the quality system is effectively implemented and maintained. The internal audit schedule is made taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The VP OPERATIONS defines the audit criteria, scope, frequency and methods. Selection of auditors and the conduct of the audits ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The VP OPERATIONS establishes the responsibilities and requirements for planning and conducting audits and for reporting the results. Audit plans, observation forms, checklists and resulting corrective and/or preventive action requests are maintained as quality records. The management responsible for the area being audited ensures that actions are taken without undue delay to eliminate detected nonconformities and their causes.

Follow-up audit activities include the verification of the actions taken and the reporting of verification results, on the corrective and preventive action form. Check sheets and/or flowcharts are developed to support audit of the quality management system requirements. The acceptability of the selected tools are to be measured by an evaluation of the effectiveness of the internal audit process and overall organization performance. The scope of the internal audits shall also include CELCO demonstrated ability meet contract and/or regulatory requirements.

8.2.3 Monitoring and Measurement of Processes:

CELCO uses suitable methods for monitoring and measurement of the quality management system processes. The monitoring and measurement activities are included in the flowcharts that are a part of this manual. These methods demonstrate the ability of the processes to achieve planned results. If planned results are not achieved, correction and/or corrective action shall be taken, as appropriate, to ensure conformity of the product.

In the event of process nonconformity, CELCO will:

- a) take appropriate action to correct the nonconforming process,
- b) evaluate whether or not the process nonconformity has resulted in product nonconformity, and
- c) identify and control the nonconforming product in accordance with paragraph 8.3.

8.2.4 Monitoring and Measurement of Product:

CELCO monitors and measures product characteristics to verify that product requirements have been met. This is carried out in accordance with the job traveler.

If key characteristics have been identified, they are monitored and controlled.

If CELCO uses sampling inspection as a means of product acceptance, the plan will be statistically valid and appropriate for use. The plan would not allow the acceptance of lots whose samples have known nonconformities. If required by contract, the plan shall be submitted for customer approval.

No product is used until it has been inspected or otherwise verified as conforming to specified requirements.

CELCO does not release product under positive-recall procedures.

Evidence of conformity with the acceptance criteria shall be maintained. Quality records shall indicate the person(s) authorizing release of product. No product will be delivered until all the operations on the job traveler have been satisfactorily completed, unless otherwise approved by the customer.

8.2.4.1 Inspection Documentation:

CELCO monitors and measures the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1) and documented procedures (see 7.5.1.1).

Measurement requirements for product acceptance are documented on the job traveler and/or referenced documents and/or drawings. Information provided includes:

- a) criteria for acceptance and/or rejection,
- b) where in the sequence measurement and testing operations are performed,
- c) a record of the measurement results, (as required by the customer), and
- d) the type of measurement instruments required and any specific instructions associated with their use.

Test records shall show actual test results data when required. Where required to demonstrate product qualification, CELCO shall ensure that records provide evidence that the product meets the defined requirements.

8.2.4.2 AEROSPACE: First Article Inspection:

CELCO provides for first article inspections. A representative part from the first production run is verified and the results recorded in accordance with the job traveler. Where required, a new first article inspection is required following any subsequent change that invalidates the previous first article inspection result.

8.2.4.2 MEDICAL: Particular requirement for active implantable medical devices and implantable medical devices

CELCO shall record (see 4.2.4) the identity of personnel performing any inspection or testing.

8.3 CONTROL OF NONCONFORMING PRODUCT PROCEDURE

CELCO ensures that product which does not conform to requirements is identified and controlled to prevent its unintended use or delivery. Nonconforming product includes nonconforming product returned from a customer. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined as follows:

Nonconforming products discovered as a result of internal processing shall be set aside, and the operator will fill out a NCR (Non conformance report). The NCR is then delivered to the Quality Manager. The customer is contacted for further instructions. If the customer requires the parts to be returned, the returned items are conspicuously marked. Upon occasion, the parts may be permanently marked for further processing to be completed.

At CELCO, Top Management may disposition nonconforming product. At CELCO, the VP Operations must approve personnel responsible for nonconforming product disposition.

CELCO may deal with nonconforming product in one or more of the following ways:

- a) by ensuring action is taken to eliminate the detected nonconformity;
- b) *by authorizing its use, release or acceptance under concession* by a relevant authority and, where applicable, by the customer;
- c) by taking action to preclude its original intended use or application.

CELCO ensures that nonconforming product is accepted by concession only if regulatory requirements are met. Records of the identity of the person(s) authorizing the concession shall be maintained (see 4.2.4).

For product processed per customer instruction, CELCO will not use dispositions of use-as-is or repair, unless specifically authorized by the customer. In addition, CELCO will not use dispositions such as use-as-is or repair if the nonconformity results in a departure from the contract requirements.

Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable, or as processed per customer instructions.

Records of the nature of nonconformities and any subsequent actions taken, including concessions are maintained as quality records. Records of nonconformance are recorded on the NCR (Non conforming Report). Non conforming quantities are recorded on the Job Traveler.

If nonconforming product is corrected, it is re-verified to demonstrate conformity to the requirements. If nonconforming product is detected after delivery or use has started, CELCO will take action appropriate to the effects, or potential effects, of the nonconformity.

If product needs to be reworked (one or more times), CELCO shall document the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented (see 4.2.3 and 7.5.1).

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

8.4 Analysis of Data:

ANALYSIS OF DATA PROCEDURE

CELCO determines, collects and analyzes data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data provides information relating to

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

Records of the results of the analysis of data shall be maintained (see 4.2.4).

8.5 Improvement:

8.5.1 Continual Improvement:

CELCO identifies and implements any changes necessary to ensure and maintain the continued suitability and 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.

If applicable, CELCO shall establish documented procedures for the issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time.

Records of all customer complaint investigations shall be maintained (see 4.2.4). If investigation determines that the activities outside CELCO contributed to the customer complaint, relevant information shall be exchanged between the organizations involved (see 4.1).

If any customer complaint is not followed by corrective and/or preventive action, the reason shall be authorized (see 5.5.1) and recorded (see 4.2.4).

If national or regional regulations require notification of adverse events that meet specified reporting criteria, CELCO shall establish documented procedures to such notification to regulatory authorities as applicable.

8.5.2 CORRECTIVE ACTION PROCEDURE

CELCO takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective action taken is appropriate to the effects of the nonconformities encountered. The procedure defining requirements for corrective action is shown below.

- a. reviewing nonconformities (including customer complaints),
- b. determining the causes of nonconformities,
- c. evaluating the need for action to ensure that nonconformities do not recur,
- d. determining and implementing action needed, *including, if appropriate, updating documentation (see 4.2)*
- e. *recording of the results of any investigation and of action taken* (see 4.2.4),
- f. reviewing corrective action taken, *and its effectiveness.*
- g. flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause, and
- h. specific actions where timely and/or effective corrective actions are not achieved.

8.5.3 PREVENTIVE ACTION PROCEDURE:

CELCO determines what action is required to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the magnitude of the potential problems. The procedure defining requirements for preventive action is shown below.

- a. determining potential nonconformities and their causes,
- b. evaluating the need for action to prevent occurrence of nonconformities,
- c. determining and implementing action needed,
- d. *recording of the results of any investigations and of action taken* (see 4.2.4) and
- e. reviewing preventive action taken *and its effectiveness.*

ATTACHMENTS: Forms used at CELCO