



Central Electropolishing Co.
Quality System Manual
ISO 9001
AS9100C
ISO 13485

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CELCO Quality Manual Revision History

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
REV H	5.6 Change schedule for management review to at least annually 5.6 Revise agenda/inputs 8.5.1 Added procedure for advisory notices 8.5.2 Revise the procedure to include action to take when timely/effective action is not achieved. 8.5.3 Revise the procedure to include controls for recording the results of preventive actions 7.5.1.3 Revise the procedure to include periodic inspection. 7.2.3 Add procedure for customer feedback	10/22/10
REV I	Revise manual to be compliant with ISO9001:2008 and AS9100C	1/3/11
REV J	Revise based on internal audit of AS9100C compliance and ISO13485 compliance as follows: Risk Management details revised Configuration Management details revised Moved Training Programs to separate document	8/16/11
REV K	Indicate procedures with title and text box	9/2/11
REV L	Remove text boxes around various information and refer to new procedures issued by the company	11/1/11
REV M	7.1.1 Revise project management to comply with AS9100C 7.1.2 Revise risk management for Risk Management Matrix	1/20/12
REV N	7.6 Revise calibration as required from Millipore audit	7/30/12
REV O	4.1 Add testing organizations to outsourced processes 7.1.2 Risk Management revised to include a watch list and based on customer history 8.2.4 Delete reference to “No sampling...”	9/12/12
REV P	4.2.4 Revise required retention of quality records from 7 years to 10 years 7.5.1.4 Added a process for this requirement. Previously considered as not applicable 7.1.2 Risk management changed to be controlled at receiving	6/24/13

REV Q	<p>4.2.3 Identify method of indicating retention of medical device obsolete documents.</p> <p>7.1.3 Configuration Management. Removed reference to one in-process project and one completed project compared to customer requirements for Configuration Audit.</p> <p>7.2.2 Revised for current activities</p> <p>7.6 Add process for review of calibration for inspection and test equipment.</p>	
REV R	<p>3. Simplify for the QMS</p> <p>7.1.2 Added Manager(s) to Quoting Removed (5% of the time) to medium (20% of the time) All Added Parts to Parts Traveler</p> <p>7.2.1 Removed CELCO does not provide post-delivery activities</p> <p>7.2.3 Removed reference to customer surveys</p> <p>7.4.1 Removed Records of this evaluation are maintained on the Approved Vendors List as temporary or customer required.</p> <p>7.5.1.2- Remove reference to procedures. Updated with personnel authorized to approve changes to production processes are listed on the Authority Matrix.</p> <p>7.5.3 Add title for QSP-07 (Medical Device Identification & Traceability)</p> <p>7.5.1.2.1, 7.5.1.2.2, 7.5.1.2.3, 7.5.1.3, 7.5.2.2 add exclusions to 4.2.2</p> <p>7.5.5 Added title to QSP-11 and QSP-08</p> <p>7.6 Rewrite: Appropriate forms will be used for each type of equipment calibrated.</p> <p>8.2.1 Revise to state customer satisfaction based on quality and OTD, secondary is complaints and related CAR's</p> <p>8.2.2 Delete sentence in third paragraph starting "The acceptability."</p>	9/22/2016

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1.0 CELCO MISSION STATEMENT/QUALITY STATEMENT

CELCO will comply with customer and applicable statutory and regulatory 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.

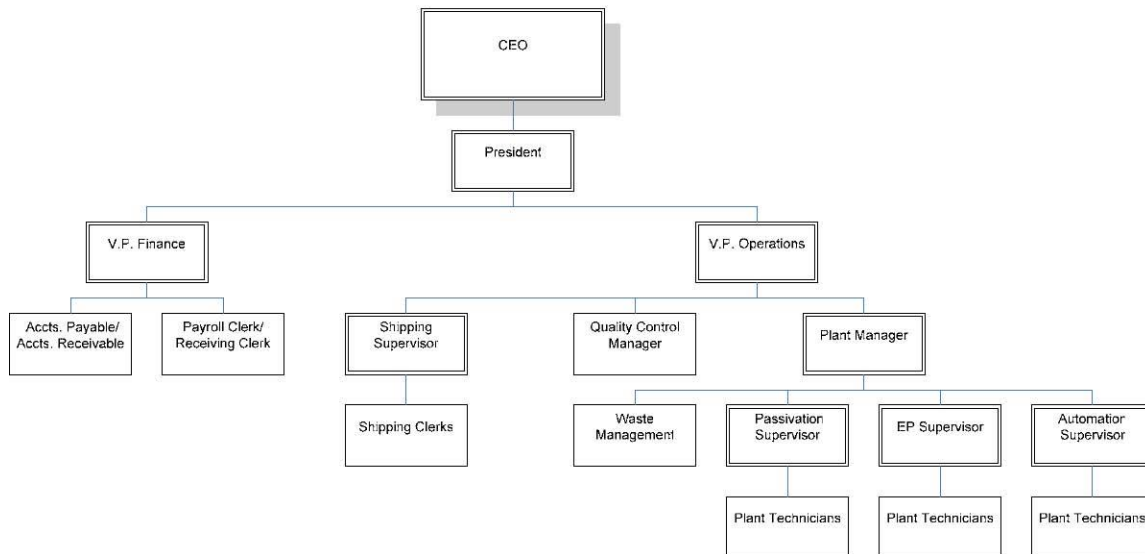
2.0 SCOPE

This manual is written to afford the responsibility of Central Electropolishing Co., Inc. also referred to as CELCO, to establish a quality management system to meet the needs of our customers and uphold the required compliance to the appropriate specifications and drawing instructions of the same clients. The requirements of any statutory and regulatory agencies will be addressed, as applicable.

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. Any reference to standards in this document are to the following revisions: ISO9001:2008, ISO13485:2003, and/or AS9100C.

Central Electropolishing Co., Inc.
Organizational Chart



3.0 QUALITY CONTROL DEPARTMENT

The VP Operations has the responsibility of developing and implementing a Quality Management System to insure that necessary compliance of customer instructions is honored. Refer to 5.5.2

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, AS9100 and ISO 13485.

CELCO has determined 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, where applicable, and analyzed to provide a baseline for data and metrics for continual improvement. Flowcharts are found on the pages following.

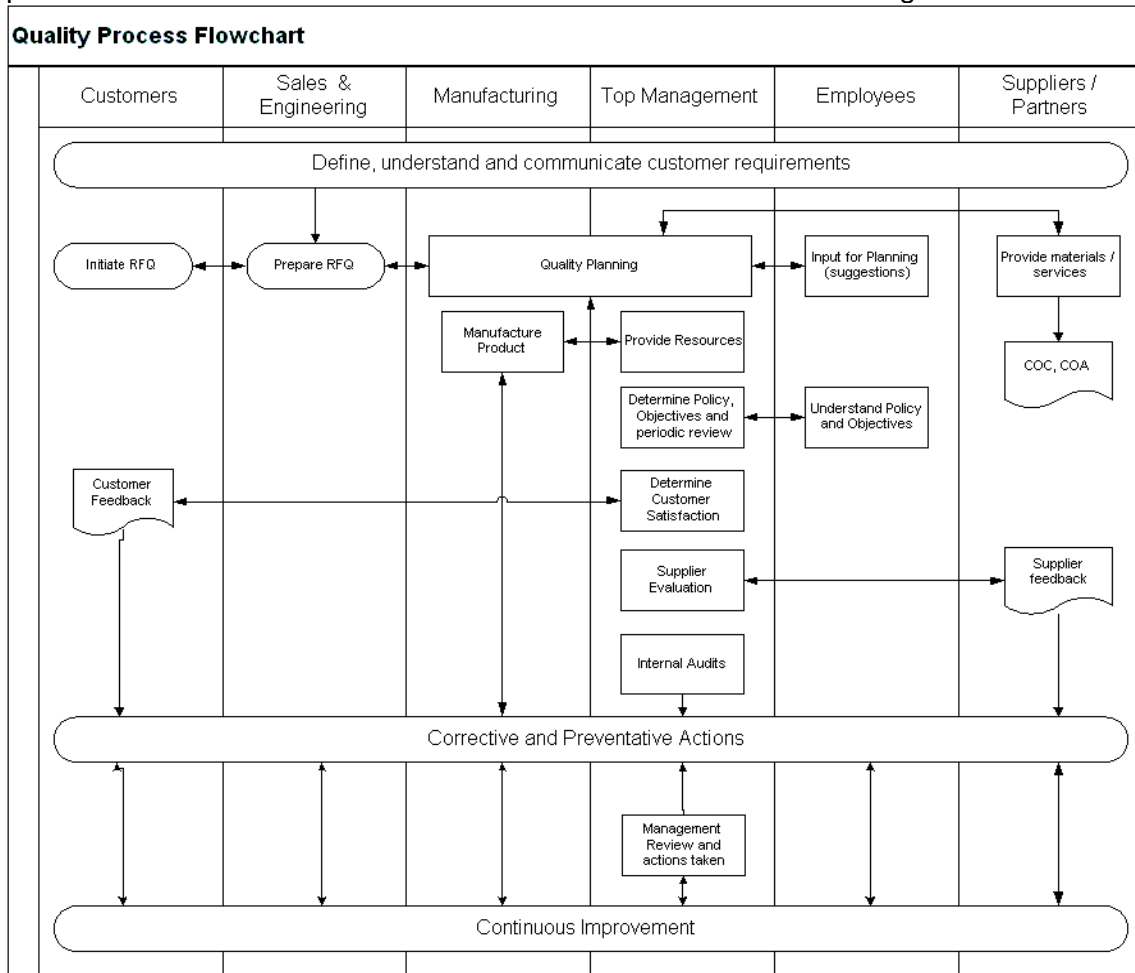
When CELCO chooses to outsource any process that affects product conformity to requirements, the organization ensures control over such processes. The type and extent of control to be applied to these outsourced processes is defined within the quality management system.

Outsourcing includes:

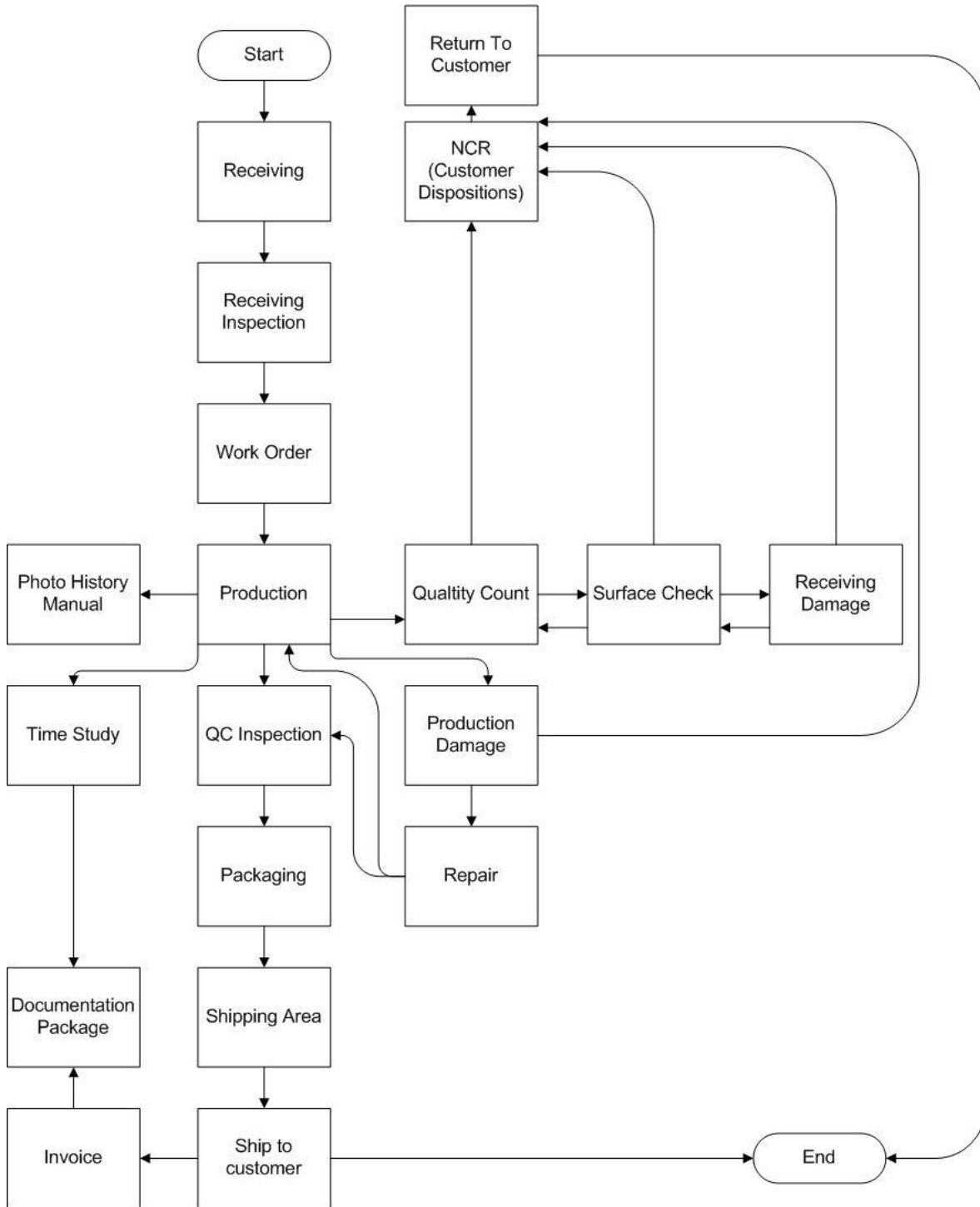
- Special processes controlled by CELCO Purchase Order and receiving inspection.
- Testing services for various processes controlled by CELCO Purchase Order and receiving inspection.
- Internal audits controlled by use of CELCO forms and review by company personnel
- Machining controlled by CELCO Purchase Order and receiving inspection
- Calibration – controlled by CELCO purchase order and record review

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

The quality processes and their interactions are shown on the flowcharts following:



CELCO – Production Flowchart



4.2 Documentation Requirements:

4.2.1 The quality management system documentation of CELCO contains all documentation required by: ISO 9001, AS9100 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 and records required by any standard addressed by this manual: (by inclusion or reference),
- d. documents, including records, determined to be necessary by CELCO to ensure the effective planning, operation and control of its processes,
- e) any other documentation specified by standards or national/regional regulations. In this case the documentation will be created, implemented and maintained.

For each type or model of medical device, CELCO establishes and maintains a file either containing or identifying documents defining product specifications and quality management system requirements (see 4.2.3). These documents define the complete manufacturing process. Installation and servicing does not apply to CELCO operations.

CELCO ensures that personnel have access to, or are aware of, relevant 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:

7.3 Design

7.5.1.2.1 Cleanliness of product and contamination control

7.5.1.2.2 Installation activities

7.5.1.2.3 Servicing activities for Medical Devices

7.5.1.3 Medical: Particular requirements for sterile medical devices

7.5.2.2 Particular requirements for sterilization processing services

8.2.4.2 Medical: Particular requirement for active implantable medical equipment and implantable medical equipment

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 AS9100 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

Documents required by the quality management system are controlled.

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: ISO9001, ISO 13485 and AS9100 standards, customer supplied data.

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

The VP Operations or authorized designee 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.

Refer to procedure QSP-01, Document Control.

Where applicable, for medical devices, CELCO ensures 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 defines the period for which at least one copy (may be electronic) of obsolete controlled documents is retained. This period ensures 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. The retention date is written on the first page of hard-copy retained obsolete documents or typed on the first page of electronic retained obsolete documents.

4.2.4 CONTROL OF RECORDS

Records are 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 procedure QSP-02, Records Control.

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.

Refer to procedure QSP-02, Records Control for control of records that are created by vendors if applicable, as well as those required by customer contract.

For medical devices, CELCO retains 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 are be stored indefinitely on computer and storage disc.

Records of (identification)	Location	Reference	Responsibility	Time (minimum)
Management reviews	Office	5.6.1	President	10 yrs
Training records	Office	6.2.2	VP Operations	10
Maintenance Records	Office	6.3	VP Operations	2

Planning of Product (Job Work Oder) (Parts Traveler) (History Sheet, including Medical)	Office	7.1	VP Operations	10
Quote reviews	Office	7.2.2	VP Operations	6 months
Contract reviews	Office	7.2.2	VP Operations	10
Purchasing Records (ID & Traceability to the extent required)	Office	7.4	VP Operations	10
Purchasing records of verification	Office	7.4	VP Operations	10
Vendor Evaluations and actions arising from the evaluation	Office	7.4	VP Operations	10
Risk Management (quote, Customer Purchase Orders, Job Work Order/Parts Traveler, and /or risk management form)	Office	7.1	VP Operations	10
Special Process records (Electropolish, Passivate, O2 Cleaning)	Office	7.5.2	VP Operations	10
Inspection and test records (in process)	Office	7.5.3	VP Operations	10
Inspection and test records (final)(release of product)	Office	8.2.4	VP Operations	10
Customer Property (if damaged)	Office	7.5.4	VP Operations	10
Calibration records (monitoring, measuring equipment)	Office	7.6	VP Operations	10
Internal audit results	Office	8.2.2	VP Operations	10
Implantable medical devices- identity of inspection personnel	Office	8.2.4.2	VP Operations	10
Nonconforming product and disposition (including waivers & concessions, if made)	Office	8.3	VP Operations	10
Medical – identity of persons making concessions	Office	8.3	VP Operations	10
Analysis of data records	Office	8.4	VP Operations	10
Corrective & Preventive actions including customer complaints, root cause investigations and follow-up	Office	8.5.2 & 8.5.3	VP Operations	10

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

5.3 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.

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. Refer to Quality Objectives document.

5.4.2 Quality Management System Planning:

Top management ensures 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 ensures the independence and authority necessary to perform these tasks.

5.5.2 Quality Management Representative:

The VP Operations, a member of CELCO's top management, 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 and unrestricted access to top management to resolve quality management issues.

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 reviews the quality management system at least 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) Quality policy and objectives
- i) Vendor re-evaluation (Vendor Risk Assessment)
- j) **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 conformity product requirements 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, Training and Awareness

CELCO determines the necessary competence for personnel performing work affecting conformity to product requirements as described above and then, where applicable, provides training or takes other actions to achieve the necessary competence. 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 (such as transport, communication or information systems) 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 are 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.

For medical devices, CELCO has established procedure QSP-09 to address product contamination. Contamination may occur in the processing media and thus contaminate the product finish but there is not a need to address requirements for health, cleanliness and clothing of personnel as such items cannot contaminate the product, work environment conditions as the environment does not have to be controlled for the CELCO processes. Special environmental conditions within the work environment do not apply.

Special arrangements are established and documented in QSP-09 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).

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 Parts 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 and documents, and to provide resources specific to the product;
- c. required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance
- d. records needed to provide evidence that the manufacturing processes and resulting product meet requirements (see 4.2.4);
- e. configuration management appropriate to the product;
- f. the identification of resources to support production.

7.1.1 Project Management

As appropriate to CELCO and the product, CELCO plans and manages product realization in a structured and controlled manner to meet the requirements at acceptable risk, within resource and schedule constraints. Each order can be identified as a project and is controlled by the Job Work Order, Parts Traveler and corresponding inspection information.

7.1.2 Risk Management

CELCO will evaluate the risks associated with all known aspects of medical device production and will review risks according to procedure QSP-14.

For all products, CELCO has established, implemented and maintains a process for managing risk to the achievement of applicable requirements that includes, as appropriate to CELCO and the product, the following:

- Responsibilities for risk management:
 - Quoting – VP/Operations, CEO, President and Manager(s). During quoting, if there are concerns about the product to be processed, the order will be no-quoted. No record is made. On time delivery is not considered a risk as the due dates are determined prior to an order being sent (during quote).
 - Contract Review – Contracts Administrator. May review input from inspection from previous orders but if the order was quoted it is accepted in all cases, pending receiving the product for inspection. Any changes in date due are resolved if different than the schedule quoted.
 - Receiving Inspection – Inspector. Upon inspection, the determination of risk is based on the condition of the product and can be refused. All risk information is entered on the Parts Traveler by the Inspector.
- Risk criteria, consequences, likelihood and risk acceptance:
 - Criteria is based on capability of product, as received, to be processed
 - Consequences can be product that does not meet the customer's requirements
 - Likelihood is very low
 - Risk acceptance is left to the Inspector, with input from management when requested.

If an order is received with additional unacceptable risk, the order may not be accepted. At any time, management can decide to accept an order with high risk but again the problem is noted on the Shop Schedule and the Parts Traveler to alert appropriate personnel.

7.1.3 Configuration Management.

CELCO has established, implemented and maintains a configuration management process that includes, as appropriate to the product:

- Configuration management planning – Begins at the time of contract acceptance (part number and revision, applicable specifications)
- Configuration identification – Identified on the Job Work Order and Parts Traveler, if applicable
- Change control – Central records for part number will be updated as required.
- Configuration status accounting – Periodic review of records may be required by management and communicated to applicable personnel.
- Configuration audit – Performed as listed on the Internal Audit schedule.

Configuration management at CELCO is maintained in conjunction with customer requirements. As part of contract review activities (customer purchase document or on-line access) the parts are reviewed and coordinated with the customer, as required.

7.1.4 Control of Work Transfers

CELCO established, implemented and maintains a process to plan and control the temporary or permanent transfer of work. For CELCO, this will only occur for a change from one vendor to another vendor. Receiving inspection will verify the conformity of the work to requirements.

The process is as follows:

- Management informs Purchasing of the need to make a change
- Purchasing reviews the Approved Vendor List
- If approved, a Purchase Order is created for the vendor identified by management
- If not approved, the vendor is approved on a temporary basis or is approved through the approval process (7.4.1)
- A Purchase Order is then sent to this new vendor.

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. 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 applicable to the product as well as any additional requirements considered necessary by CELCO.

7.2.2 Review of Requirements Related to the Product:

CELCO reviews requirements related to the product. This review is 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. Special requirements of the product are determined, and
- e. Risks are identified, including risk for short lead times, as stated in paragraph 7.1.2.

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.

Evidence of Contract Review/Acceptance of order is the completed Job Work Order.

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.

7.3 Design and Development

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

7.4 Purchasing:

7.4.1 Purchasing Process:

CELCO ensures that purchased product conforms to specified requirements. The type and extent of control applied to the vendor and the purchased product, is dependent upon the effect of the purchased product on the quality of our product. **Refer to QSP-15, Purchasing.** CELCO is responsible for the conformity of all products purchased from vendors, including any product from sources defined by the customer.

CELCO evaluates and selects vendors based on their ability to supply product in accordance with the stated requirements. Criteria for initial selection are included in an evaluation based on the New Vendor Form which includes potential risk in quality and delivery based on CELCO requirements. Customer required vendors will be added without evaluation. Certification to a known standard when required by a customer is used as criteria when applicable.

CELCO maintains a list of its vendors that includes the scope of their approval. The list will only include approved vendors. Any vendor considered conditional or disapproved will be used only with approval management and available in the accounting software of the company.

Vendors are re-evaluated by CELCO at least annually, based on the performance of the vendor related to the effect on risk for quality, delivery and response to concerns using the Vendor Risk Assessment form. The results of these reviews are maintained and used as a factor in establishing the level of controls to be implemented. When vendors do not meet requirements, a corrective action request will be issued to the vendor. Any vendor that fails to satisfactorily complete a corrective action request may be removed from the approved vendor's list. Records of the results of evaluations and any necessary corrective actions arising from evaluations are maintained as quality records.

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

Management has the responsibility for approving new vendors and has the authority to disapprove the use of sources. This process is contained in the management review and those in attendance have the responsibility to input into the decision for any changes in the status of a vendor.

Management determines the risk involved with selecting or using a vendor. Selection is based on inclusion on the Approved Vendor List where risk has been evaluated annually on the Vendor Risk Assessment form. New vendor risk is based on the information included on the New Vendor Form.

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 identification and revision status specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data,
- e. requirements for design, test, inspection, verification (including production process verification, use of statistical techniques for product acceptance and related instructions for acceptance by CELCO, and as applicable critical items including key characteristics,
- f. requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing,
- g. requirements regarding the need for the vendor to notify CELCO of nonconforming product and obtain CELCO approval for nonconforming product disposition, notify CELCO of changes in product and/or process, changes of vendors, changes of manufacturing facility location and, where required, obtain CELCO approval and flow down to the supply chain the applicable requirements including customer requirements,
- h. records retention requirements;
- i. right of access by CELCO, the customer of CELCO, and regulatory authorities to the applicable areas of the facilities, at any level of the supply chain, involved in the order and to all applicable records, and

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

To the extent required for traceability given in 7.5.3.2, CELCO maintains 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 vendors including: accompanying documentation, certificate of conformity, test reports, statistical records, and process control records,
- b. inspection and audit at vendor's premises,
- c. review of the required documentation, and
- d. inspection of materials upon receipt.

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

CELCO periodically validates test reports on raw material.

CELCO does not delegate verification activities to a vendor.

Where CELCO or the customer of CELCO intends to perform verification at the vendor's premises, these verification arrangements and the method of product release is contained in the purchasing information.

Verification by the customer is not used by CELCO as evidence of effective control of quality by the vendor and does 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 plans and carries out processing in accordance with the applicable procedures and operations in sequence on the Parts 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 equipment as needed,
- e) implementation of monitoring and measurement as required by the product,
- f) implementation of product 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/verification operations have been completed as planned, or as otherwise documented and authorized,
- i) provision for the prevention, detection, and removal of foreign objects,
- j) monitoring and control of utilities and supplies (water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements, and
- k) criteria for workmanship, specified in the clearest practical manner (written standards, representative samples, illustrations).
- l) **the implementation of defined operations for labeling and packaging. CELCO establishes and maintains 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 is verified and approved using the Parts Traveler and History Sheet. A batch can be a single medical device.**

CELCO considers the following when planning the processing of product, as appropriate:

- the establishment of process controls and development of control plans where key characteristics have been identified,
- designing, manufacturing, and using tooling to measure variable data,
- identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization,
- special processes (see 7.5.2).

7.5.1.1 Production Process verification:

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

7.5.1.2 Control Of Production Process Changes:

Personnel authorized to approve changes to production processes are listed on the Authority Matrix.

CELCO will identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.

CELCO will control and document changes affecting processes, production equipment, tools or software programs.

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

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 Software Programs:

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

Validation prior to production use includes verification of the first article produced to the specification. Re-inspection may include first part buy-off.

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

7.5.1.3 MEDICAL: Particular requirements for sterile medical devices

CELCO does not provide sterilization processing services.

7.5.1.4 Post Delivery Support

Post-delivery support provide as applicable and deemed for the:

- a. Collection and analysis of data related to actions by CELCO after product has been shipped to customers.
- b. Corrective actions or corrections to be made, including investigation and reporting, when problems are detected after delivery.
- c. Control and updating of technical documentation, if required, after action has been taken,
- d. Approval, control and use of repair/rework plans as applicable to the situation, and
- e. Determining controls required for off-site work if the work is to be done at the customer's facilities.

The primary record for actions taken and their results will be a corrective action request and related records referred to in that record.

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

Validation of Processes for Production and Service Provision: CELCO validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation demonstrates the ability of these processes to achieve planned results.

CELCO establishes arrangements for these processes including, as applicable

- a. defined criteria for review and approval of the processes – defined by the specification,

- b. approval of equipment and qualification of personnel – based on training and proven competency,
- c. use of specific methods and procedures – defined by the specification,
- d. requirements for records (see 4.2.4), and
- e. revalidation – if required based on the changes to the specification.
- 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:

Where appropriate, CELCO identifies the product by suitable means throughout product realization and has developed QSP-07 (Medical Device Identification & Traceability) for traceability of medical devices. Record control is listed in section 4.2.4.

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

CELCO has established QSP-07 to ensure that medical devices returned to the organization are identified and distinguished from conforming product.

CELCO maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration. Records are maintained using the Parts Traveler.

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

When acceptance authority media are used (e.g., stamps and/or initials), CELCO has established and documents controls for the media. 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.

Where traceability is a requirement, CELCO controls and records the unique identification of the product on the Parts Traveler (see 4.2.4).

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

- a. identification to be maintained throughout the product life (Parts Traveler);
- b. batch control where required (Parts Traveler),
- 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 for medical devices, Parts Travelers)

7.5.3.2 Traceability

7.5.3.2.1 General

CELCO has established QSP-07 for traceability. It defines the extent of product traceability and the records required (see 4.2.4, 8.3 and 8.5). See above.

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

In defining the records required for traceability, CELCO includes records of materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements. This is not the case as the production facility is controlled as required.

CELCO provides processing services for the customer only.

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

7.5.3.3 Status identification

The identification of product status is maintained throughout processing and storage of the product to ensure that only product that has passed the required inspections.

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, CELCO reports this to the customer and maintain records. 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:

CELCO does not have any product that has a limited shelf life or special storage conditions. In the event that the company would get any such material as a special requirement or process improvement, QSP-11, Medical Shelf Life applies. CELCO does store products in accordance with customer requirements. Product preservation is addressed in procedure QSP-08, Medical Device Preservation.

CELCO preserves the conformity of product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. This preservation includes identification, handling, packaging, storage and protection. Preservation also applies (if appropriate) to the component parts of a product. As applicable, preservation of product includes, where applicable in accordance with product specifications and/or applicable statutory and 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 (QSP-11);
- 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 Equipment

CELCO determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to specified requirements. Refer to QSP-16, Calibration.

CELCO maintains a list of measuring equipment that defines the process employed for their calibration/verification including details of unique identification (item identification number), equipment type (item description), certification date, calibration method, test standard, QC initials (person performing the calibration), calibration due date and status of tool (location). and acceptance criteria. The list of equipment 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 testing being performed.

Where necessary to ensure valid results, measuring equipment is:

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

CELCO has established, implemented and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification. Inspection monitors due dates of measuring equipment as appropriate. When equipment is due, he assures that the calibration/verification is performed and recorded.

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

In addition, the quality function assesses and records the validity of the previous measuring results if the equipment is found to be out-of-calibration. CELCO will take appropriate action for the equipment and any product affected. Refer to QSP-16 for action to be taken.

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 is confirmed. This is undertaken prior to initial use and reconfirmed as necessary.

Instrument Calibration Frequency and Records:

- Profilometer measurement pads will be certified annually to the pads' original reading. Profilometers are checked daily before use and during the day with these test pads.
- Micrometers will be calibrated traceable to NIST every five years but checked monthly with gage blocks.
- Thermometers and hydrometers are calibrated annually.
- Voltmeters and ammeters are checked every six months with certified voltmeters and ammeters. Every two years the master Voltmeter/Ammeter is calibrated.
- Stop watches are verified for accuracy using a master stop watch and tracked by a serial number. The master stop watch is replaced every two years.

The Calibration Log (will be completed denoting the instrument identification number, item description, date of calibration, method, standards, quality control initial, calibration due date and status of tool (location). The hydrometer, thermometer and other certifications will be filed with the Calibration Log. These certifications will be filed in the Quality (Inspection) office. Appropriate forms will be used for each type of equipment calibrated.

As directed by the Vice President/Quality Manager calibration status is reviewed for all equipment using a copy of the lists of calibrated equipment. Each item verified is checked off the list as in-calibration or noted as out-of-calibration on the same list. If out-of-calibration, the equipment is taken out of service and reported to the Vice President/Quality Manager, actions are assigned and the lists are filed.

8. MEASUREMENT, ANALYSIS AND IMPROVEMENT:

8.1 General:

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

- a) demonstrate conformity to product requirements,
- 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:

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.

Information to be monitored and used for the evaluation of customer satisfaction is quality to customers and on-time delivery performance. Customer complaints and corrective action requests related to complaints are used as a secondary measure of customer satisfaction. CELCO has developed and implemented a plan for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results. The plan is based on the corrective action process in section 8.5.2 of this manual and the related procedure.

This procedure QSP-12 provides for a feedback system 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 will form part of the feedback system (see 8.5.1).

8.2.2 Internal Audit

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 ISO9001, AS9100, 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 do 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. Management ensures that any necessary corrections and corrective 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 scope of the internal audits also includes CELCO demonstrated ability meet contract and/or regulatory requirements.

For details to conducting an internal audit, refer to QSP-03, Internal Quality Audits. This procedure defines the responsibilities and requirements for planning and conducting audits, establishing records and reporting results. Records of internal audits are maintained per the records control requirements of CELCO.

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 Process Maps that are a part of this manual or

attached to it. These methods demonstrate the ability of the processes to achieve planned results. If planned results are not achieved, correction and/or corrective action is taken, as appropriate.

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,
- c) determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and
- d) identify and control the nonconforming product (see 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 Parts Traveler. Evidence of the conformity with the acceptance criteria is maintained.

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

If CELCO uses sampling inspection as a means of product acceptance, the plan will be statistically valid and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability). The plan would not allow the acceptance of lots whose samples have known nonconformities. If required by contract, the plan will 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.

Quality records indicate the person(s) authorizing release of product for delivery to the customer. No product will be delivered until all the operations on the Parts Traveler have been satisfactorily completed, unless otherwise approved by the customer.

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

8.2.4.1 Inspection Documentation:

CELCO monitors and measures the characteristics of the product to verify that product requirements have been met. This is performed at appropriate stages of the product realization process in accordance with the Parts Traveler (see 7.1) and documented procedures, if applicable (see 7.5.1.1). CELCO records (see 4.2.4) the identity of personnel performing any inspection. This is recorded on the Parts Traveler.

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

Excluded from the QMS.

8.3 Control Of Nonconforming Product

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. Procedure QSP-04, Control of Nonconforming Product, defines the controls and related responsibilities and authorities for dealing with nonconforming product.

Nonconforming products discovered as a result of internal processing are set aside, and the operator will fill out a NCR (Nonconformance 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.

Where applicable, 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.
- d) By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

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 are maintained on the Parts Traveler or shipping documentation (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 is 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 (Nonconforming Report. Nonconforming quantities are recorded on the Parts 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 documents the rework process on a Parts Traveler specially printed for that activity. It will be issued from the same authorization and approval as the original Parts Traveler. Prior to authorization and approval of the rework and Parts Traveler, a determination of any adverse effect of the rework upon product is made and documented on the Parts Traveler (see 4.2.3 and 7.5.1).

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

CELCO's procedure QSP-04, defines the responsibility and authority for the review and disposition of nonconforming product and the process for approving personnel making these decisions.

8.4 Analysis of Data:

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 (see 8.2.1)
- b) conformity to product requirements, (see 8.2.4)
- c) characteristics and trends of processes and products including opportunities for preventive action, (see 8.2.3 and 8.2.4), and
- d) vendors (see 7.4)

Records of the results of the analysis of data are maintained (see 4.2.4). Refer to QSP-17, Data Analysis.

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.

CELCO has established procedure QSP-10 for the issue and implementation of advisory notices.

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

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

Customer complaint are recorded as corrective actions.

If national or regional regulations require notification of adverse events that meet specified reporting criteria, CELCO addresses the requirement using procedure QSP-13.

8.5.2 Corrective Action

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 QSP-05, Corrective Action, defines requirements for corrective action.

Corrective action will include:

- a. The Corrective Action Record (CAR) is used to review nonconformities (including customer complaints),
- b. On the CAR, determination the causes of nonconformities is recorded,
- c. The evaluation of the need for action to ensure that nonconformities do not recur is determined and noted on the form,
- d. The action to be taken is determined and implemented action as needed, including, if appropriate, updating documentation (see 4.2)
- e. the results of any investigation and of action taken is recorded on the CAR (see 4.2.4),
- f. When complete, the Management Representative will review the corrective action taken, and its effectiveness.
- g. Corrective action can be issued to a vendor, when it is determined that the vendor is responsible for the root cause. The Management Representative will monitor CAR's issued to vendors.
- h. If the action to be taken is not completed in a timely manner (within the allotted time for action), more time may be given or other action may be taken based on the situation (discipline for employees, discontinuance of use for a vendor, etc.)
- i. If effective corrective actions are not achieved, the Management Representative can give more time to the action, require an alternative action is determined and implemented, and require those involved to re-visit cause and possible actions and/or discontinue the CAR.
- j. Determine if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.

8.5.3 Preventive Action

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 QSP-06, Preventive Action, defines requirements for preventive action. In some cases, the PAR form will be used to track proposed improvements and management review action items.

Preventive action will include:

- a. A Preventive Action Record (PAR) is initiated for the potential nonconformities and their causes,
- b. The form will also include the evaluation of the need for action to prevent occurrence of nonconformities,
- c. Once the need for action is confirmed, the action needed will be determined and implemented,

- d. The PAR will record the results of any investigations and of action taken (see 4.2.4) and
- e. When complete, the Management Representative will review preventive action taken and its effectiveness.
- f. If not effective, more time will be provided or alternative action recommended.
- g. All records for a specific preventive action is recorded on the PAR and filed when complete.