




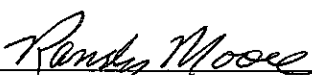
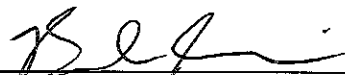
Central Electropolishing Co. Quality System Manual

ISO 13485:2016

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Revision History

Revision Level	Change Description	Date
New	Original Release without AS9100 requirements Previous revisions available with last revision of the combination manual	4/19/2017
A	Added references to procedures Revised for conformance to all requirements of ISO13485:2016	6/22/18
B	4.1.3 Added reference to conformance to process maps, Job History Sheets, etc. 4.2.3 Added reference to Job History Sheet and its review and approval	11/20/18
C	4.1.6 Added reference to software validation procedure 4.1.1 Added statement regarding exclusions to the QMS 5.6.1 Added reference to management review procedure 6.2 Added reference to competency procedure 6.4.1 Change to an exclusion as not relevant to Celco processes	12/11/18
D	8.2.6 Revised to show records of equipment used for test and inspection	12/12/18
E	4.1.1 Included phrase "not applicable", "not just exclusion" 7.5.3 Changed from "exclusion" to "not applicable" 7.5.5 Changed from "exclusion" to "not applicable" 7.5.7 Changed from "exclusion" to "not applicable" 7.5.9.2 Changed from "exclusion" to "not applicable" 6.4.1 included (previously not applicable)	10/15/19
F	7.5.4 Servicing changed to "Not Applicable"	08/31/20

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1. SCOPE

This Quality Manual includes ISO 13485 quality management system requirements and specifies additional regulatory requirements, as applicable.

It is emphasized that the requirements specified in this manual are complementary (not alternative) to customer and applicable statutory and regulatory requirements.

If there is a conflict between the requirements of this manual and customer or applicable statutory or regulatory requirements, the latter takes precedence.

This Quality Manual specifies requirements for the quality management system to:

- a) demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
- b) enhance customer satisfaction through the effective application of the QMS, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements

The scope of the Quality Management System is "Electropolishing and Passivation of Stainless Steel".

2. NORMATIVE REFERENCES

ISO 9000:2015 Quality management systems – Fundamentals and vocabulary

ISO 9001:2015 Quality management systems – Requirements

ISO 13485:2016 - Medical Devices – Quality Management Systems – Requirements for regulatory purposes

3. TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in ISO 13485 and the following apply:

3.1. ADVISORY NOTICE: Notice issued by the organization subsequent to delivery of the medical device, to provide supplementary information or to advise on action to be taken in the:

- Use of a medical device,
- Modification of a medical device,
- Return of the medical device to CELCO that supplied it, or
- Or destruction of a medical device

3.2. AUTHORIZED REPRESENTATIVE: Natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation.

3.3. CLINICAL EVALUATION: Assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer.

3.4. COMPLAINT: Written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from CELCO's control or related to a service that affects the performance of such medical devices.

3.5 DISTRIBUTOR: Natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.

3.6. IMPLANTABLE MEDICAL DEVICE: Medical device which can only be removed by medical or surgical intervention and which is intended to:

- be totally or partially introduced into the human body or a natural orifice, or
- replace an epithelial surface or the surface of the eye, and
- remain after the procedure for at least 30 days

3.7. IMPORTER: Natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.

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3.8. LABELLING: label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

3.9. LIFE-CYCLE: All phases in the life of a medical device, from the initial conception to final decommissioning and disposal

3.10. MANUFACTURER: Natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s)

3.11. MEDICAL DEVICE: Instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices
- providing information by means of in vitro examination of specimens derived from the human body;

3.12. MEDICAL DEVICE FAMILY: Group of medical devices manufactured by or for the same organization and having the same basic design and performance characteristics related to safety, intended use and function.

3.13. PERFORMANCE EVALUATION: Assessment and analysis of data to establish or verify the ability of an in vitro diagnostic medical device to achieve its intended use.

3.14. POST-MARKET SURVEILLANCE: Systematic process to collect and analyze experience gained from medical devices that have been placed on the market

3.15. PRODUCT: Result of a process (Service, Software, Hardware, Processed materials)

3.16. PURCHASED PRODUCT: Product provided by a party outside CELCO's quality management system.

3.17. RISK: Combination of the probability of occurrence of harm and the severity of that harm.

3.18. RISK MANAGEMENT: Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk.

3.19. STERILE BARRIER SYSTEM: Minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.

3.20. STERILE MEDICAL DEVICE: Medical device intended to meet the requirements for sterility.

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4. CELCO QUALITY MANAGEMENT SYSTEM

4.1. GENERAL REQUIREMENTS

4.1.1 Celco has established, implemented, maintained, and continually improves their quality management system, including the processes needed and their interactions, in accordance with the requirements of ISO13485, current revision. Exclusions to the CELCO QMS or requirements that are not applicable to CELCO QMS, are identified in the appropriate section of this Quality Manual.

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

4.1.2 CELCO:

- a) determines the processes needed for the quality management system and the application of these processes throughout CELCO taking into account the roles undertaken by CELCO;
- b) applies a risk based approach to the control of the appropriate processes needed for the quality management system;
- c) determines the sequence and interaction of these processes.

4.1.3 For each quality management system process, CELCO:

- a) determines criteria and methods needed to ensure that both the operation and control of these processes are effective;
- b) ensures the availability of resources and information necessary to support the operation and monitoring of these processes;
- c) implements actions necessary to achieve planned results (conformance to process maps, Job History Sheets, etc) and maintain the effectiveness of these processes;
- d) monitors, measures as appropriate, and analyzes these processes;
- e) establishes and maintains records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements.

4.1.4 CELCO manages these quality management system processes in accordance with the requirements of ISO13485 and applicable regulatory requirements. Changes to be made to these processes are:

- a) evaluated for their impact on the quality management system;
- b) evaluated for their impact on the medical devices produced under this quality management system;
- c) controlled in accordance with the requirements of this International Standard and applicable regulatory requirements.

4.1.5 When CELCO chooses to outsource any process that affects product conformity to requirements, CELCO monitors and ensures control over such processes. CELCO retains responsibility of conformity to ISO13485 and to customers and applicable regulatory requirements for outsourced processes. Controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4. The controls include written quality agreements.

4.1.6 CELCO documented procedures (refer to QSP-19, Software Validation) for the validation of the application of computer software used in the quality management system. Such software applications are validated prior to initial use and, as appropriate, after changes to such software or its application.

Specific approach and activities associated with software validation and revalidation are proportionate to the risk associated with the use of the software.

Currently no software used by CELCO requires validation.

4.2. DOCUMENTATION REQUIREMENTS

4-2.1 GENERAL

CELCO's quality management system documentation includes:

- a) documented statements of a quality policy and quality objectives;
- b) a quality manual;
- c) documented procedures and records required by this International Standard;
- d) documents, including records, determined by CELCO to be necessary to ensure the effective planning, operation, and control of its processes (Not listed in this manual but referenced on the Master List of Controlled Documents);

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- e) other documentation specified by applicable regulatory requirements.

4.2.2. QUALITY MANUAL

CELCO document a quality manual includes:

- a) the scope of the quality management system, including details of and justification for any exclusion or non-application;
- b) the documented procedures for the quality management system, or reference to them;
- c) a description of the interaction between the processes of the quality management system.

CELCO quality manual outlines the structure of the documentation used in the quality management system.

4.2.3. MEDICAL DEVICE FILE

For each medical device type or medical device family, CELCO establishes and maintains one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements.

The content of the file(s) include, but is not limited to:

- a) general description of the medical device, intended use/purpose, and labelling, including any instructions for use;
- b) specifications for product;
- c) specifications or procedures for manufacturing, packaging, storage, handling and distribution;
- d) procedures for measuring and monitoring;
- e) as appropriate, requirements for installation;
- f) as appropriate, procedures for servicing.

The Job History Sheet is used for communicating all applicable information to Production. Each Job History Sheet is developed by the Vice-President/Operations and reviewed for adequacy by the Vice-President.

4.2.4. CONTROL OF DOCUMENTS

Documents required by the quality management system are controlled. Records are a special type of document and are controlled according to the requirements given in 4.2.5.

Documented procedure (QSP-01) defines the controls needed to:

- a) review and approve documents for adequacy prior to issue;
- b) review, update as necessary and re-approve documents;
- c) ensure that the current revision status of and changes to documents are identified;
- d) ensure that relevant versions of applicable documents are available at points of use;
- e) ensure that documents remain legible and readily identifiable;
- f) ensure that documents of external origin, determined by CELCO to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled;
- g) prevent deterioration or loss of documents;
- h) prevent the unintended use of obsolete documents and apply suitable identification to them.

CELCO ensures that changes to documents are reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions.

CELCO defines the period for which at least one copy of obsolete documents shall be 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 CELCO, but not less than the retention period of any resulting record, or as specified by applicable regulatory requirements.

4.2.5. CONTROL OF RECORDS

Records are maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

CELCO's document procedure (QSP-02) defines the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.

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CELCO defines and implements methods for protecting confidential health information contained in records in accordance with applicable regulatory requirements.

Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable.

CELCO retains the records for at least the lifetime of the medical device as defined by CELCO, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by CELCO.

5. MANAGEMENT RESPONSIBILITY

5.1. MANAGEMENT COMMITMENT

Top management provides evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:

- a) communicating to CELCO the importance of meeting customer as well as applicable regulatory requirements;
- b) establishing the quality policy;
- c) ensuring that quality objectives are established;
- d) conducting management reviews;
- e) ensuring the availability of resources.

5.2 CUSTOMER FOCUS

Top management ensures that customer requirements and applicable regulatory requirements are determined and met.

5.3 QUALITY POLICY

Top management ensures that the quality policy:

- a) is applicable to the purpose of CELCO;
- b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system;
- c) provides a framework for establishing and reviewing quality objectives;
- d) is communicated and understood within CELCO;
- e) is reviewed for continuing suitability.

5.4. PLANNING

5.4.1. QUALITY OBJECTIVES

Top management ensures that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within CELCO. The quality objectives are measurable and consistent with the quality policy.

5.4.2. QUALITY MANAGEMENT SYSTEM PLANNING

Top management ensures that:

- a) the planning of the quality management system is carried out in order to meet the requirements, as well as the quality objectives;
- b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5. RESPONSIBILITY, AUTHORITY AND COMMUNICATION

5.5.1. RESPONSIBILITY AND AUTHORITY

Top management ensures that responsibilities and authorities are defined, documented and communicated within CELCO.

Top management documents 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. See Authority Matrix and Organizational Chart.

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5.5.2. MANAGEMENT REPRESENTATIVE

Top management has appointed the VP Operations, a member of management who, irrespective of other responsibilities, has responsibility and authority that includes:

- a) ensuring that processes needed for the quality management system are documented;
- b) reporting to top management on the effectiveness of the quality management system and any need for improvement;
- c) ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout CELCO. .

5.5.3. INTERNAL COMMUNICATION

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

5.6. MANAGEMENT REVIEW

5.6.1. GENERAL

CELCO performs management reviews at least annually in conjunction with all requirements of the two certifications that CELCO holds. This is done to ensure the continuing suitability, adequacy and effectiveness of the quality management system. The review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Refer to procedure QSP-20, Management Review.

5.6.2. REVIEW INPUT

The input to management review include, but is not limited to, information arising from:

- a) feedback
- b) complaint handling;
- c) reporting to regulatory authorities;
- d) audits;
- e) monitoring and measurement of processes;
- f) monitoring and measurement of product;
- g) corrective action;
- h) preventive action;
- i) follow-up actions from previous management reviews;
- j) changes that could affect the quality management system;
- k) recommendations for improvement;
- l) applicable new or revised regulatory requirements.

5.6.3. REVIEW OUTPUT

The output from management review is recorded and includes the input reviewed and any decisions and actions related to:

- a) improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes;
- b) improvement of product related to customer requirements;
- c) changes needed to respond to applicable new or revised regulatory requirements;
- d) resource needs.

6. RESOURCE MANAGEMENT

6.1. PROVISION OF RESOURCES

CELCO determines and provides the resources needed to:

- a) implement the quality management system and to maintain its effectiveness;
- b) meet applicable regulatory and customer requirements.

6.2. HUMAN RESOURCES

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

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CELCO documents the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel. Refer to procedure QSP-21, Competency.

CELCO:

- a) determines the necessary competence for personnel performing work affecting product quality;
- b) provides training or take other actions to achieve or maintain the necessary competence;
- c) evaluates the effectiveness of the actions taken;
- d) ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives;
- e) maintains appropriate records of education, training, skills and experience.

6.3. INFRASTRUCTURE

CELCO documents the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure is documented as follows:

- a) buildings, workspace and associated utilities;
 - (Electropolishing) 10,000 square feet for one facility and 1200 square feet for the other (Midwest)
 - Large facility (480, 230 and 110 volt power)
 - Smaller facility (230 and 110 volt power)
 - 10,000 square feet facility includes inspection and shipping areas
 - 1200 square feet facility includes O2 cleaning area
 - Clean water needs to be available for both processes
- b) process equipment (hardware);
 - Electropolishing tanks with rectifiers, racks/fixtures and equipment to move product
 - Inspection equipment (hydrometers, thermometers, profilometers, micrometers and calipers)
- c) supporting services
 - Transport using company vehicles and contracted shipping services
 - Communication using the company phone system and wi-fi capabilities
 - Information systems using computers, printers and networks

CELCO documents requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements apply to equipment used in production, the control of the work environment and monitoring and measurement.

6.4. WORK ENVIRONMENT AND CONTAMINATION CONTROL

6.4.1. WORK ENVIRONMENT

CELCO documents the requirements for the work environment needed to achieve conformity to product requirements.

If the conditions for the work environment can have an adverse effect on product quality, CELCO documents the requirements for the work environment in the Work Order and/or the procedures to monitor and control the work environment.

CELCO:

- a) documents requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance;
- b) ensures that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person

6.4.2. CONTAMINATION CONTROL

As appropriate, CELCO plans and documents arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product.

For sterile medical devices, this requirement is excluded as it is not relevant to CELCO processes.

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7. PRODUCT REALIZATION

7.1. PLANNING OF PRODUCT REALIZATION

CELCO plans and develops the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.

CELCO documents one or more processes for risk management in product realization. Records of risk management activities are maintained.

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

- a) quality objectives and requirements for the product;
- b) the need to establish processes and documents and to provide resources specific to the product, including infrastructure and work environment;
- c) required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance;
- d) records needed to provide evidence that the realization processes and resulting product meet requirements.

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

7.2. CUSTOMER-RELATED PROCESSES

7.2.1 DETERMINATION OF REQUIREMENTS RELATED TO PRODUCT

CELCO determines:

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- b) requirements not stated by the customer but necessary for specified or intended use, as known;
- c) applicable regulatory requirements related to the product;
- d) any user training needed to ensure specified performance and safe use of the medical device;
- e) any additional requirements determined by CELCO.

7.2.2. REVIEW OF REQUIREMENTS RELATED TO PRODUCT

CELCO reviews the requirements related to product. This review is conducted prior to CELCO's commitment to supply product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensures that:

- a) product requirements are defined and documented;
- b) contract or order requirements differing from those previously expressed are resolved;
- c) applicable regulatory requirements are met;
- d) any user training identified in accordance with 7.2.1 is available or planned to be available;
- e) CELCO has the ability to meet the defined requirements.

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

When 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. COMMUNICATION

CELCO plans and documents arrangements for communicating with customers in relation to:

- a) product information,
- b) enquiries, contracts or order handling, including amendments;
- c) customer feedback, including complaints;
- d) advisory notices.

Refer to QSP-18 Contract Review, QSP-12 Medical Device Customer Feedback and QSP-10 Medical Device Advisory Notices for more details for these communications with customers and possibly regulatory/statutory authorities.

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CELCO communicates with regulatory authorities in accordance with applicable regulatory requirements.

7.3. DESIGN AND DEVELOPMENT

CELCO takes an exclusion to section 7.3, Design and Development as it only processes products based on customer provision.

7.4. PURCHASING

7.4.1. PURCHASING PROCESS

CELCO documented procedure (QSP-15) ensure that purchased product conforms to specified purchasing information,

CELCO establishes criteria for the evaluation and selection of suppliers. The criteria is:

- a) based on the supplier's ability to provide product that meets CELCO's requirements;
- b) based on the performance of the supplier
- c) based on the effect of the purchased product on the quality of the medical device;
- d) proportionate to the risk associated with the medical device.

CELCO plans the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product are monitored. The results of the monitoring, provides an input into the supplier re-evaluation process.

Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.

Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities are maintained.

7.4.2. PURCHASING INFORMATION

Purchasing information is describes or references the product to be purchased, including as appropriate:

- a) product specifications;
- b) requirements for product acceptance, procedures, processes and equipment;
- c) requirements for qualification of supplier personnel;
- d) quality management system requirements,

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

Purchasing information includes, as applicable, a written agreement that the supplier notify CELCO of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.

To the extent required for traceability CELCO maintains relevant purchasing information in the form of documents and records.

7.4.3. VERIFICATION OF PURCHASED PRODUCT

CELCO establishes and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities are based on the supplier evaluation results and proportionate to the risks associated with the purchased product.

When CELCO becomes aware of any changes to the purchased product, CELCO determines whether these changes affect the product realization process or the medical device.

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

Records of the verification are maintained..

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7.5. PRODUCTION AND SERVICE PROVISION

7.5.1. CONTROL OF PRODUCTION AND SERVICE PROVISION

Production and service provision are planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls includes but are not limited to

- a) documentation of procedures and methods for the control of production,
- b) qualification of infrastructure;
- c) implementation of monitoring and measurement of process parameters and product characteristics;
- d) availability and use of monitoring and measuring equipment,
- e) implementation of defined operations for labelling and packaging;
- f) implementation of product release, delivery and post-delivery activities.

CELCO establishes and maintains a record for each medical device or batch of medical devices that provides traceability to the extent specified and identifies the amount manufactured and amount approved for distribution. The records, Job History Sheets, are verified and approved.

7.5.2. CLEANLINESS OF PRODUCT

CELCO documents requirements for cleanliness of product or contamination control of product if:

- a) product is cleaned by CELCO prior to sterilization or its use;
- b) product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or its use;
- c) product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use;
- d) product is supplied to be used non-sterile, and its cleanliness is of significance in use;
- e) process agents are to be removed from product during manufacture.

If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4.1 do not apply prior to the cleaning process.

7.5.3. INSTALLATION ACTIVITIES

CELCO determined that section 7.5.3, Installation Activities, does not apply to the QMS as the company only processes product supplied by a customer.

7.5.4. SERVICING ACTIVITIES

CELCO determined that section 7.5.4, Servicing Activities, does not apply to the QMS as the company does not provide any servicing for the medical devices that are processed for a customer.

7.5.5. PARTICULAR REQUIREMENTS FOR STERILE MEDICAL DEVICES

CELCO has determined that section 7.5.5 does not apply as the company does not process any medical devices requiring sterilization.

7.5.6. VALIDATION OF PROCESSES FOR PRODUCTION AND SERVICE PROVISION

CELCO validates any processes for production and service provision where the resulting output cannot be or is not 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 consistently.

CELCO documents for validation of CELCO processes (PV-01 and PV-02), including:

- a) defined criteria for review and approval of the processes;
- b) equipment qualification and qualification of personnel;
- c) use of specific methods, procedures and acceptance criteria;
- d) as appropriate, statistical techniques with rationale for sample sizes;
- e) requirements for records
- f) revalidation, including criteria for revalidation;
- g) approval of changes to the processes.

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CELCO does not use any software in the production processes.

Records of the results and conclusion of validation and necessary actions from the validation are maintained.

7.5.7. PARTICULAR REQUIREMENTS FOR VALIDATION OF PROCESSES FOR STERILIZATION AND STERILE BARRIER SYSTEMS

CELCO has determined that section 7.5.7 does not apply as the company does not process any medical devices requiring sterilization.

7.5.8. Identification

CELCO documented procedures (QSP-07) for product identification and identify product by suitable means throughout product realization.

CELCO identifies product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status is maintained throughout production, storage, installation and servicing of 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.

If required by applicable regulatory requirements, CELCO documents a system to assign unique device identification to the medical device.

CELCO documented procedures (QSP-07) to ensure that medical devices returned to CELCO are identified and distinguished from conforming product.

7.5.9. Traceability

7.5.9.1. General

CELCO documented procedure (QSP-07) for traceability. This procedure defines the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained.

7.5.9.2. Particular requirements for implantable medical devices

CELCO has determined that section 7.5.9.2 does not apply as the company does not process any implantable medical devices.

7.5.10. Customer property

CELCO identifies, verifies protects, and safeguards customer property provided for use or incorporation into the product while it is under CELCO's control or being used by CELCO. If any customer property is lost, damaged or otherwise found to be unsuitable for use, CELCO reports this to the customer and maintain records.

7.5.11. Preservation of product

CELCO documented procedure (QSP-08) for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation applies to the constituent parts of a medical device.

CELCO protects product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by:

- a) designing and constructing suitable packaging and shipping containers;
- b) documenting requirements for special conditions needed if packaging alone cannot provide preservation.

If special conditions are required, they are controlled and recorded.

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 determined requirements.

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CELCO documented procedure (QSP-16) to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

As necessary to ensure valid results, measuring equipment shall:

- a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards: when no such standards exist, the basis used for calibration or verification are recorded;
- b) be adjusted or re-adjusted as necessary: such adjustments or re-adjustments are recorded;
- c) have identification in order to determine its calibration status,
- d) be safeguarded from adjustments that would invalidate the measurement result;
- e) be protected from damage and deterioration during handling, maintenance and storage.

CELCO performs calibration or verification in accordance with documented procedures.

In addition, CELCO assess and records the validity of the previous measuring results when the equipment is found not to conform to requirements. CELCO takes appropriate action in regard to the equipment and any product affected.

CELCO does not use software for the monitoring and measurement of requirements.

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8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1. General

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

- a) demonstrate conformity of product;
- b) ensure conformity of the quality management system;
- c) maintain the effectiveness of the quality management system.

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

8.2. Monitoring and measurement

8.2.1. Feedback

As one of the measurements of the effectiveness of the quality management system, CELCO shall gather and monitor information relating to whether CELCO has met customer requirements. The methods for obtaining and using this information shall be documented.

CELCO documented procedure (QSP-12) for the feedback process. This feedback process includes provisions to gather data from production as well as post-production activities.

The information gathered in the feedback process serves as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.

If applicable regulatory requirements require CELCO to gain specific experience from postproduction activities, the review of this experience shall form part of the feedback process.8.2.2

8.2.2. Complaint handling

CELCO's documented procedure (QSP-12) for timely complaint handling in accordance with applicable regulatory requirements.

These procedures include sat a minimum requirements and responsibilities for:

- a) receiving and recording information;
- b) evaluating information to determine if the feedback constitutes a complaint;
- c) investigating complaints;
- d) determining the need to report the information to the appropriate regulatory authorities;
- e) handling of complaint-related product;
- f) determining the need to initiate corrections or corrective actions.

If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process is documented.

If an investigation determines activities outside CELCO contributed to the complaint, relevant information is exchanged between CELCO and the external party involved..

8.2.3. Reporting to regulatory authorities

If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, CELCO documents procedures for providing notification to the appropriate regulatory authorities.

Records of reporting to regulatory authorities is maintained.

8.2.4. Internal audit

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

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- a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by CELCO, and applicable regulatory requirement
- b) is effectively implemented and maintained.

CELCO documents a procedure (QSP-03) to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.

An audit program is planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

Records of the audits and their results, including identification of the processes and areas audited and the conclusions, are maintained.

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

8.2.5. Monitoring and measurement of processes

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

8.2.6. Monitoring and measurement of product

CELCO monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures.

Evidence of conformity to the acceptance criteria shall be maintained. The identity of the person authorizing release of product is recorded. Records identify the specific test equipment used to perform measurement activities.

Product release and service delivery shall not proceed until the planned and documented arrangements have been satisfactorily completed.

8.3. Control of nonconforming product

8.3.1. General

CELCO ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. CELCO documents a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation and disposition of nonconforming product.

The evaluation of nonconformity shall include a determination of the need for an investigation and notification and the rationale for decisions shall be maintained.

Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions shall be maintained.

8.3.2. Actions in response to nonconforming product detected before delivery

CELCO deals with nonconforming product by one or more of the following ways:

- a) taking action to eliminate the detected nonconformity;
- b) taking action to preclude its original intended use or application;
- c) authorizing its use, release or acceptance under concession.

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CELCO ensures that nonconforming product is accepted by concession only if the justification is provided, approval is obtained and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession shall be maintained.

8.3.3. Actions in response to nonconforming product detected after delivery

When nonconforming product is detected after delivery or use has started, CELCO takes action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken shall be maintained.

CELCO's documented procedure (QSP-10) for issuing advisory notices in accordance with applicable regulatory requirements. These procedures shall be capable of being put into effect at any time. Records of actions relating to the issuance of advisory notices are maintained.

8.3.4. Rework

CELCO seldom performs rework but if required, this rework will be performed in accordance with documented procedures and/or instructions to perform the work. These will take into account the potential adverse effect of the rework on the product, if any. These procedures undergo the same review and approval as the original procedure or instructions for the work to be performed.

After the completion of rework, product is verified to ensure that it meets applicable acceptance criteria and regulatory requirements.

8.4. Analysis of data

CELCO's documented procedure (QSP-17) to determine, collect and analyze appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures include determination of appropriate methods, including statistical techniques and the extent of their use.

The analysis of data includes data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from:

- a) feedback;
- b) conformity to product requirements;
- c) characteristics and trends of processes and product, including opportunities for improvement;
- d) suppliers;
- e) audits;
- f) service reports, as appropriate.

If the analysis of data shows that the quality management system is not suitable, adequate or effective, CELCO shall use this analysis as input for improvement as required in 8.5.

8.5 Improvement

8.5.1. General

CELCO identifies and implements any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, post market surveillance, analysis of data, corrective actions, preventive actions and management review.

8.5.2. Corrective action

CELCO takes action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions are proportionate to the effects of the nonconformities encountered.

CELCO's documented procedure (QSP-05) to define requirements for: reviewing nonconformities (including complaints);

- a) determining the causes of nonconformities;
- b) evaluating the need for action to ensure that nonconformities do not recur;
- c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;

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- d) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
- e) reviewing the effectiveness of corrective action taken.

8.5.3. Preventive action

CELCO determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems.

CELCO's documented procedure (QSP-06) to describe requirements for:

- a) determining potential nonconformities and their causes;
- b) evaluating the need for action to prevent occurrence of nonconformities;
- c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
- d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
- e) reviewing the effectiveness of the preventive action taken, as appropriate.