CELCO

Central Electropolishing Co.
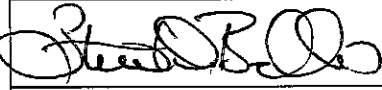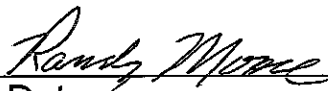## Quality System Manual

Revision B

ISO 9001:2015/AS9100D:2016

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REVISION HISTORY

Revision Level	Change Description	Date
New	Original Release of AS9100 manual after deletion of ISO13485 requirements	11/10/17
A	Cover - Revise references to standard current revision 8.4.2 – Changed vendor re-evaluation to 3 years Delete references to COTO Log Changed Business Manager to Contracts Manager	10/12/18
B	Removed ISO 9000:2015 Quality management systems – Fundamentals and vocabulary 5.2.2 Removed: At least annually, during a quarterly management review, the quality manual, policy and quality objectives are reviewed for continuing suitability. 7.4 Removed: CELCO accomplishes this by periodic employee briefings and/or quality information placed on the bulletin board regarding objectives, goals and quality system audit results 8.1.4 Removed Valid raw material mill certifications or certified test reports shall be required for all raw materials with proof of being supplied by customer approved sources as applicable. Added: When required by Purchase Order, valid raw material mill certifications or certified test reports shall be required for all raw materials with proof of being supplied by customer approved sources and/or distributors/manufacturers listed in the specification for the material, as applicable. 8.5.1.1 Removed: Preventive maintenance of Production equipment currently in use is performed by the General Manager. Daily checks of equipment are performed by operators, but no record is maintained. 8.7.1 Added: 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. Records will be maintained.	8/13/2020

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1. SCOPE

This Quality Manual for Central Electro-Polishing Quality Management System is based on AS9100D and includes ISO 9001:2015 quality management system requirements and specifies additional aviation, space, and defense industry requirements, definitions, and notes.

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

All the requirements of this manual are specific only to Central Electro-Polishing and the products and services it provides.

2. NORMATIVE REFERENCES

The following documents, whole or in part, are referenced in this document and are used for its application to the Quality Management System of Central Electro-Polishing:
ISO 9001:2015 Quality Management Systems – Requirements
AS9100 - Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations

3. TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in ISO 9000:2015 and the following apply:

3.1 Counterfeit Part

An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer. Further defined as follows for section 8.1.4 of this Quality Manual:
   a) Suspect Part/ Product - A part or product in which there is an indication by visual inspection, testing or other information that may have been misrepresented by the supplier or manufacturer and may meet the definition of a counterfeit part.
   b) Counterfeit Part/ Product - A suspect part or product that is a copy or substitute without legal right or authority to do so or one whose material, performance, or characteristics are knowingly misrepresented by a supplier in the supply chain.
   c) Counterfeit Work - Work that is or contains items, misrepresented as having been designed and/or produced under an approved system or other acceptable method. The term also includes approved work that has reached a design life limit or has been damaged beyond possible repair, but is altered and misrepresented as acceptable.

3.2 Critical Items

Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the provision and use of the products and services; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

3.3 Key Characteristic

An attribute or feature whose variation has a significant effect on product fit, form, function,

performance, service life, or producibility, that requires specific actions for the purpose of controlling variation.

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

3.5 Special Requirements
Those requirements identified by the customer, or determined by CELCO, which have high risks of not being met, thus requiring their inclusion in the operational risk management process. Factors used in the determination of special requirements include product or process complexity, past experience, and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by CELCO to be at the limit of its technical or process capabilities

4. CONTEXT OF CENTRAL ELECTRO-POLISHING

4.1 Understanding Central Electro-Polishing, Inc. and Its Context

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

CELCO monitors and reviews information about these external and internal issues. They are as follows:

- External
  - ➢ Vendor Support - Owners monitor and measure vendor performance to support day-to-day operations
  - ➢ Technology – New technology for CELCO processes is reviewed when available. New equipment needs are reviewed with new technology as applicable.
- Internal
  - ➢ Performance analysis – Track sales, expenses, quality and delivery time to customers and other business metrics deemed necessary
  - ➢ Competitive position – Using performance analysis, control operating costs and product expenses to give customers competitive quotes.

4.2 Understanding the Needs and Expectations of Interested Parties

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

a) the interested parties that are relevant to the quality management system and their needs/expectations are as follows:
  - ➢ Internal
    - Owners – Profit, operations as required, care of the facilities and equipment
    - Management – Authority, input into operations
    - Employees – Adequate equipment/tools, training, infrastructure, pay/benefits
  - ➢ External
    - Customers – Quality products on-time
    - Vendors – Adequate product/service information and lead times

4.3 Determining the Scope of the Quality Management System

CELCO determines the boundaries and applicability of the quality management system to establish its scope.

CELCO established and maintains a quality management system that includes:
  a) the scope of the quality management system, including details of and justification for any sections that don't apply. CELCO considers section 8.3 Design and Development of Products and Services as not applicable since CELCO manufactures products to customer-provided designs. This does not affect CELCO's ability or responsibility to ensure the conformity of products and service or the enhancement of customer satisfaction.
  b) the documented procedures established for the quality management system, or reference to them. As necessary, documented information is referenced in this manual.
  c) description of the interaction between the processes of the quality management system. Refer to the Quality Management System Process Map/Interactions

The scope is as follows:
Central Electro-Polishing, Inc. provides precision-machined parts and components for the aerospace industry.

4.4 Quality Management System and Its Processes

4.4.1 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 AS9100, current revision.

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

CELCO determines the processes (refer to Process maps) needed for the quality management system and their application throughout CELCO, and:

a) determines the inputs required and the outputs expected from these processes;
b) determines the sequence and interaction of these processes;
c) determines and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
d) determines the resources needed for these processes and ensure their availability;
e) assigns the responsibilities and authorities for these processes;
f) address the risks and opportunities as determined in accordance with the requirements of 6.1;
g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
h) improve the processes and the quality management system.

4.4.2 To the extent necessary, CELCO:

a) maintains documented information to support the operation of its processes;
b) retains documented information to have confidence that the processes are being carried out as planned.

CELCO established and maintains documented information that includes:

a) a general description of relevant interested parties (see 4.2);
b) the scope of the quality management system, including boundaries and applicability (see 4.3);
c) a description of the processes needed for the quality management system and their application throughout CELCO (see QMS Process Map/Interactions and Product Realization Process maps);
d) the sequence and interaction of these processes (see QMS Process Map/Interactions and Product Realization Process maps);
e) assignment of the responsibilities and authorities for these processes (see Authority Matrix and Process Maps).

5. LEADERSHIP

5.1 Leadership and Commitment

5.1.1 General
Top management demonstrates leadership and commitment with respect to the quality management system by:
   a) taking accountability for the effectiveness of the quality management system;
   b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of CELCO;
   c) ensuring the integration of the quality management system requirements into CELCO's business processes;
   d) promoting the use of the process approach and risk-based thinking;
   e) ensuring that the resources needed for the quality management system are available;
   f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
   g) ensuring that the quality management system achieves its intended results;
   h) engaging, directing, and supporting persons to contribute to the effectiveness of the quality management system;
   i) promoting improvement;
   j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer Focus
Top management demonstrates leadership and commitment with respect to customer focus by ensuring that:
   a) customer and applicable statutory and regulatory requirements are determined, understood, and consistently met;
   b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
   c) the focus on enhancing customer satisfaction is maintained;
   d) product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved.

5.2 Policy

5.2.1 Establishing the Quality Policy
Top management established, implemented, and maintains the quality policy that:
   a) is appropriate to the purpose and context of CELCO and supports its strategic direction;
   b) provides a framework for setting quality objectives;
   c) includes a commitment to satisfy applicable requirements;
   d) includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the Quality Policy
The quality policy:
   a) is available and maintained as documented information;
   b) is communicated, understood, and applied within CELCO;
   c) is available to relevant interested parties, as appropriate.

5.3 CELCO Roles, Responsibilities, and Authorities
Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within CELCO.
Top management assigns the responsibility and authority for:
   a) ensuring that the quality management system conforms to the requirements of AS9100 International Standard;
   b) ensuring that the processes are delivering their intended outputs;
   c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;

d) ensuring the promotion of customer focus throughout CELCO;

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

Top management has appointed the VP Operations of CELCO's management, identified as the management representative (MR), who has the responsibility and authority for oversight of the above requirements.

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

The responsibility of the MR includes liaison with external parties on matters relating to the quality management system.

6. PLANNING

6.1 Actions to Address Risks and Opportunities

6.1.1 When planning for the quality management system, CELCO considers the issues referred to in section 4.1, the requirements referred to in 4.2 and the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result(s);
b) enhance desirable effects;
c) prevent, or reduce, undesired effects;
d) achieve improvement.

6.1.2 CELCO plans:

a) actions to address these risks and opportunities;
b) how to:
  1. integrate and implement the actions into its quality management system processes (see 4.4);
  2. evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services.

6.2 Quality Objectives and Planning to Achieve Them

6.2.1 CELCO establishes quality objectives at relevant functions, levels, and processes needed for the quality management system.

The quality objectives:

a) are consistent with the quality policy;
b) are measurable;
c) take into account applicable requirements;
d) are relevant to conformity of products and services and to enhancement of customer satisfaction;
e) are monitored;
f) are communicated;
g) are updated, as appropriate.

CELCO maintains documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, CELCO determines:

a) what will be done;
b) what resources will be required;
c) who will be responsible;
d) when it will be completed;
e) how the results will be evaluated.

6.3 Planning of Changes

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

CELCO considers:

a) the purpose of the changes and their potential consequences;
b) the integrity of the quality management system;
c) the availability of resources;
d) the allocation or reallocation of responsibilities and authorities.

7. SUPPORT

7.1 Resources

7.1.1 General

CELCO determines and provides the resources needed for the establishment, implementation, maintenance, and continual improvement of the quality management system.

CELCO considers:
a) the capabilities of, and constraints on, existing internal resources;
b) what needs to be obtained from external providers.

7.1.2 People

CELCO determines and provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

CELCO determines, provides, and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

7.1.4 Environment for the Operation of Processes

CELCO determines, provides, and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.

These factors can differ substantially depending on the products and services provided.

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

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

CELCO ensures that the resources provided:
a) are suitable for the specific type of monitoring and measurement activities being undertaken;
b) are maintained to ensure their continuing fitness for their purpose.

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

7.1.5.2 Measurement Traceability

When measurement traceability is a requirement, or is considered by CELCO to be an essential part of providing confidence in the validity of measurement results, measuring equipment is:
a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification is retained as documented information;
b) identified in order to determine their status;
c) safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results

CELCO established, implemented, and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification. Calibrations are tracked, recorded and planned for frequency.

CELCO maintains a register of the monitoring and measuring equipment. The register includes the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria. The list also states the date as when the tool is due for calibration.

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

CELCO determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and takes appropriate action as necessary. If there is a possibility that nonconforming or suspect product has been delivered, the customer will be contacted by a member of management. Records will be maintained based on the communication with the customer and the feedback received from the customer.

If any equipment is still sealed after its calibration cycle has expired, CELCO personnel can apply a sticker to extend the date another cycle. If the seal has to be damaged in the process of trying to remove it, the old sticker is left in place. It is marked out if possible. The later seal has precedence on the due date.

7.1.6 Organizational Knowledge
CELCO determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

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

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

7.2 Competence
CELCO:
a) determines the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
b) ensures that these persons are competent on the basis of appropriate education, training, or experience;
c) where applicable, takes actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
d) retains appropriate documented information as evidence of competence

7.3 Awareness
CELCO ensures that persons doing work under CELCO's control are aware of:
a) the quality policy;
b) relevant quality objectives;
c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
d) the implications of not conforming with the quality management system requirements;
e) relevant quality management system documented information and changes thereto;
f) their contribution to product or service conformity;
g) their contribution to product safety;
h) the importance of ethical behavior.

7.4 Communication
CELCO determines the internal and external communications relevant to the quality management system, including:
a) what it will communicate;
b) when to communicate;
c) with whom to communicate;
d) how to communicate;
e) who communicates.

7.5 Documented Information
7.5.1 General
CELCO's quality management system includes:
- a) documented information required by this applicable standard;
- b) documented information determined by CELCO as being necessary for the effectiveness of the quality management system.

7.5.2 Creating and Updating
When creating and updating documented information, CELCO ensures appropriate:
- a) identification and description (e.g., a title, date, author, or reference number);
- b) format (e.g., language, software version, graphics) and media (e.g., paper, electronic);
- c) review and approval for suitability and adequacy.

CELCO established the following process for creating and/or updating documented information:
- When creating and updating documented information, CELCO ensures, as applicable:
  - a) Document title, date, approval
  - b) Form title, revision, approval by issue from the Management Representative;
  - c) Documented information is created electronically with hard copies issued as required (forms may be issued as hard copy and then scanned/saved electronically);
  - d) Reviewed and approved for suitability and adequacy when initially issued and when a revision issued
- To add or revise documented information, a draft may be created and given to the MR.
- The draft is reviewed and approved as directed by the MR. No record is made of review.
- Once reviewed, it is approved as required by the person designated to approve the document/form.
- The Master List of Controlled Documents is updated with the new document or the new revision except for forms.
- Hard copies of the document/form are made as required. All documented information is controlled electronically and/or printed on blue paper.
- Electronic copies of documented information are controlled for alteration.
- Training is performed as required for the new information.

7.5.3 Control of Documented Information
7.5.3.1 Documented information required by the quality management system and by the referenced standards is controlled to ensure:
- a) it is available and suitable for use, where and when it is needed;
- b) it is adequately protected (e.g., from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, CELCO addresses the following activities, as applicable:
- a) distribution, access, retrieval, and use;
- b) storage and preservation, including preservation of legibility;
- c) control of changes (e.g., version control);
- d) retention and disposition;
- e) prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

CELCO has developed the following process for control of documented information:
- For the control of documented information, CELCO addresses the following activities, as applicable, using the Master List of Controlled Documents and the Quality System Records Control matrix:
  - a) distribution, access, retrieval, and use;
  - b) storage and preservation, including preservation of legibility;
  - c) control of changes (e.g., revision/version control);

d) retention and disposition (Quality Manual, procedures, manual attachments, process maps and forms are shredded/deleted when replaced by a new revision).
- Documented information is retained as evidence of conformity shall be protected from unintended alterations by hard copy control and scanning as read-only.
- Documented information controlled electronically is protected as follows:
  a) Master file of the documented information that provides unauthorized changes and unintended alteration
  b) Access is provided as required by the use of the file and the purpose of the access
  c) Copies of the master files are used to create revisions by approved personnel
  d) Copies of the customer-supplied master files are used for programming by approved personnel (DPD/MBD)
  e) Back-ups of the network are created and kept off-site on a regular basis depending on the type of file to provide protection from loss.

Documented information of external origin determined by CELCO to be necessary for the planning and operation of the quality management system is identified as appropriate and controlled. This includes customer Part files (including digital files).

For specific control of records for identification, storage, protection, retrieval, retention and disposition of records, refer to the Quality System Records Control matrix which includes the requirements for controlling records that are retained by vendors.

Records are maintained so they remain legible, readily identifiable, and retrievable.

Disposition of documented information that reach their retention period or are no longer applicable is defined as follows:
- Hard copy records are shredded
- electronic/digital files and/or records are deleted)

8. OPERATION

8.1 Operational Planning and Control

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

a) determining the requirements for the products and services;
b) establishing criteria for:
   1. the processes;
   2. the acceptance of products and services;
c) determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services;
d) implementing control of the processes in accordance with the criteria;
e) determining, maintaining, and retaining documented information to the extent necessary:
   1. to have confidence that the processes have been carried out as planned;
   2. to demonstrate the conformity of products and services to their requirements;
f) determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;
g) engaging representatives of affected CELCO functions for operational planning and control;
h) determining the process and resources to support the use and maintenance of the products and services;
i) determining the products and services to be obtained from external providers;
j) establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

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

The output of this planning is suitable for CELCO's operations.

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

CELCO ensures that outsourced processes are controlled (8.4.2).

CELCO established, implements, and maintains a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements. The process ensures that work transfer impacts and risks are managed and is controlled using a Purchase Order and Receiving Inspection as follows:

- The Approved Vendors List is reviewed for possible vendors of the work to be transferred,
- If there is no supplier available, a new supplier can be found and approved, including assessment of potential risk. If this is deemed a "one-time" use, this vendor does not have to be included as an approved vendor.
- A quote is received if deemed necessary,
- A Purchase Order is developed and issued with necessary requirements, and
- Receiving inspection is performed for the first order and any follow on orders, as deemed necessary on the Parts Traveler, to verify conformance to requirements. This is recorded on the Parts Traveler.

8.1.1 Operational Risk Management

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 Manager. 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 Parts Traveler to alert appropriate personnel.

8.1.2 Configuration Management
CELCO plans, implements, and controls a process for configuration management as appropriate to CELCO and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process:
   a) Controls product identity and traceability to requirements, including the implementation of identified changes;
   b) Ensures that the documented information (e.g., requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services.

8.1.3 Product Safety
CELCO plans, implements, and controls the processes needed to assure product safety during the entire product life cycle, as appropriate to CELCO and the product. The process is as follows:
a) Assessment of hazards and mitigation of associated risks
   - All information related to product safety must be controlled for potential action to be taken during Management reviews.
   - Identify potential problems relating to product and processes and address these problems, considered as risk(s).
   - Monitor safety related to the key processes for provision of products (8.1). Document at Management review for any issues found.
   - Identify and mitigate risks relating to the organization and its personnel (human factors, management of responsibilities) as identified by management.
   - Management of safety critical items - Define and implement a monitoring plan for critical items identified through problem identification and safety analysis that are deemed a risk.
   - All risks and opportunities are reviewed at Management Review.
b) Analyze and report of occurred events affecting safety
   - The following information is tracked by Management review's. Any required action is reviewed at Management Review.
   - Develop a list of potential and actual safety related events and determine potential impacts or actual impact on the company.
   - Organize the information to share by external reporting to interested parties, as deemed necessary by management.
   - Analyze any adverse trends of products in use reliability and define appropriate actions during Management review.
   - Communicate these events and train personnel (7.3):

- o Promote safety culture and lessons learned from occurred events (impacts of the parts delivered by the organization on the final product safety)
- o Prevent occurrence of safety issued by taking into account industry experience (including occurrences on other products with similar functions or based on same technologies or components).

Flow down requirements for product safety through the communication of the vendor's contribution to product safety. This is done with a Purchase Order.

8.1.4 Prevention of Counterfeit Parts
CELCO plans, implements, and controls processes, appropriate to CELCO and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer. Refer to definitions in section 3.1.

The CELCO process is as follows:
a) Procurement of raw material, hardware and products, as applicable, shall be procured through customer approved sources as defined by customer approved supplier listings in accordance with Vendor Evaluation/Re-evaluation.
b) When required by Purchase Order, valid raw material mill certifications or certified test reports shall be required for all raw materials with proof of being supplied by customer approved sources and/or distributors/manufacturers listed in the specification for the material, as applicable.
c) Certifications of Conformance shall be required on all hardware and products such as hardware, sealant, etc. where specific requirements such as specifications are imposed.
d) All raw material and products shall be processed through the verification of purchased product process at receipt in accordance with requirements for receiving inspection. This shall include verification of raw material mill certifications, certified test reports or certifications of conformance to ensure compliance to requirements.
e) As required by receiving inspection, product shall not be released for use until verified as conforming.
f) Parts that do not conform to imposed requirements or are found to be counterfeit in nature shall be handled in accordance with Control of Nonconforming Product, section 8.7.
g) In the event that counterfeit parts or product are identified through the verification of purchased product process, the applicable supplier shall be notified and formal corrective action will be required. If this is the case, the customer representative shall also be notified in writing of the identification of counterfeit parts.
h) Disposition of the questionable product is determined from the outcome of the investigation of the product.

8.2 Requirements for Products and Services

8.2.1 Customer Communication
Communication with customers includes:
a) providing information relating to products and services;
b) handling enquiries, contracts, or orders, including changes;
c) obtaining customer feedback relating to products and services, including customer complaints;
d) handling or controlling customer property;
e) establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the Requirements for Products and Services
When determining the requirements for the products and services to be offered to customers, CELCO ensures that:
a) the requirements for the products and services are defined, including:
1. any applicable statutory and regulatory requirements;
2. those considered necessary by CELCO;

b) CELCO can meet the claims for the products and services it offers;
c) special requirements of the products and services are determined;
d) operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified

8.2.3 Review of the Requirements for Products and Services
8.2.3.1 CELCO ensures that it has the ability to meet the requirements for products and services to be offered to customers. CELCO conducts a review before committing to supply products and services to the customer, to include:
a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
c) requirements specified by CELCO;
d) statutory and regulatory requirements applicable to the products and services;
e) contract or order requirements differing from those previously expressed.

This review is coordinated with applicable personnel/functions of CELCO.

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

CELCO ensures that contract or order requirements differing from those previously defined are resolved.[1]

The customer requirements are confirmed by CELCO before acceptance, when the customer does not provide a documented statement of their requirements.

Records of the results of the review and actions arising from the review are maintained with the customer's Purchase Order and the issuance of a Parts Traveler by Receiving Inspection. The Contracts Administrator enters the order into the system. When required, acknowledgement of orders is performed by the Contracts Administrator and the email used for acknowledgement is maintained.

Where the customer provides no documented statement of requirement, the customer requirements are confirmed by the company before acceptance. An email may be kept as evidence of the order and acknowledgement. The customer may be required to provide some evidence of order placement.

8.2.3.2 CELCO retains documented information, as applicable:
a. on the results of the review;
b. on any new requirements for the products and services.

8.2.4 Changes to Requirements for Products and Services
CELCO ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and Development of Products and Services (Not applicable)

8.4 Control of Externally Provided Processes, Products, and Services
8.4.1 General
CELCO ensures that externally provided processes, products, and services conform to requirements.

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

CELCO ensures, when required, that customer-designated or approved external providers (includes Vendors, vendors and subcontractors), including process sources (e.g., special processes), are used.

CELCO identifies and manages the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers.

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

CELCO determines the controls to be applied to externally provided processes, products, and services when:
- a) products and services from external providers are intended for incorporation into CELCO's own products and services;
- b) products and services are provided directly to the customer(s) by external providers on behalf of CELCO;
- c) a process, or part of a process, is provided by an external provider as a result of a decision by CELCO.

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

8.4.1.1 CELCO:
- a) defines the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;
- b) maintains a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);
- c) periodically reviews external provider performance including process, product and service conformity, and on-time delivery performance;
- d) defines the necessary actions to take when dealing with external providers that do not meet requirements;
- e) defines the requirements for controlling documented information created by and/or retained by external providers

CELCO maintains a list of approved vendors that includes the scope of their approval. All vendors in the system are approved.

CELCO evaluates and selects vendors based on their ability to supply product in accordance with the stated requirements. For new vendors, the following process is used:
- a) The New Vendor Form is completed with vendor information and product/service.
- b) Vendor may be initially maintained as a temporary supplier. This will be noted on the New Vendor Form.
- c) There are three categories for initial assessment included on the New Vendor Form.
- d) Vendors may be approved without the stated criteria if required by a customer.

e) Once all requirements are considered addressed by Purchasing, The supplied can be considered approved.

Vendor risk will be evaluated annually at Management Review by feedback from persons with authority to conduct purchasing (see Authority Matrix).

Vendors are re-evaluated by CELCO every three years prior to re-registration, based on the performance of the supplier as noted on the Vendor Re-evaluation form. Records of the results of evaluations are maintained by management.

When vendors do not meet requirements, a corrective action request may be issued to the vendor. Any vendor that fails to satisfactorily complete a corrective action request may be removed from the approved supplier's list but this is determined by management.

Where required, CELCO and vendors use customer-approved special process sources. In some cases, the customer may specify a material supplier that is not on their approved supplier list or on CELCO's list. This is allowed by the CELCO quality management system and the final determination is made by management as to whether or not they are added.

8.4.2 Type and Extent of Control
CELCO ensures that externally provided processes, products, and services do not adversely affect it's ability to consistently deliver conforming products and services to its customers.

CELCO:
a) ensures that externally provided processes remain within the control of its quality management system;
b) defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
c) takes into consideration:
   - the potential impact of the externally provided processes, products, and services on CELCO's ability to consistently meet customer and applicable statutory and regulatory requirements;
   - the effectiveness of the controls applied by the external provider;
   - the results of the periodic review of external provider performance (see 8.4.1.1 c);
d) determines the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements

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

Where CELCO chooses to outsource any process that affects product conformity to requirements, it ensures control over such processes.

When externally provided 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.

When CELCO delegates verification activities to the external provider, the scope and requirements for delegation is defined and a register of delegations is maintained. CELCO periodically monitor the external provider's delegated verification activities.

Certificates of Conformance (COC) are required from suppliers and used to verify externally provided products. When test reports are required from a material supplier on the Purchase Order, they will be used to verify externally provided products. Receiving or Quality personnel attain a copy of the material specification and compare the results shown in the Test Report to the specification

requirements. Any discrepancy is noted on the test report. When complete, the report is initialed and dated and given to Purchasing. Discrepancies will result in segregation of the material until resolution. This material is considered counterfeit, refer to 8.1.4.

When a customer or CELCO has identified raw material as a significant operational risk (e.g., critical items), CELCO implements a process to validate the accuracy of test reports. The process is as follows:

a) Management will determine when the process is to be implemented.
b) Material is ordered from an approved vendor with a request for a test report as well as the certificate of analysis (COA) from the vendor.
c) When received the test report may be verified as compared to the specification for that material by Quality.
d) If deemed necessary, a random sample of at-risk material is sent to an approved lab for verification. Go to f) below.
e) If a sample is sent, the report from the lab is reviewed. If no sample is sent, the COA from the vendor will be used.
f) Any discrepancy noted by either review will result in corrective action to the vendor. If material of the tested lot number has resulted in parts to a customer, the customer will be notified, and action will be taken as required.

8.4.3 Information for External Providers
CELCO ensures the adequacy of requirements prior to their communication to the external provider.

CELCO communicates to external providers its requirements for:
a) the processes, products, and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions);
b) the approval of:
   - products and services;
   - methods, processes, and equipment;
   - the release of products and services;
c) competence, including any required qualification of persons;
d) the external providers' interactions with CELCO;
e) control and monitoring of the external providers' performance to be applied by CELCO;
f) verification or validation activities that CELCO, or its customer, intends to perform at the external providers' premises;
g) special requirements, critical items, or key characteristics;
h) test, inspection, and verification (including production process verification);
i) the use of statistical techniques for product acceptance and related instructions for acceptance by CELCO;
j) the need to:
   - implement a quality management system;
   - use customer-designated or approved external providers, including process sources (e.g., special processes);
   - notify CELCO of nonconforming processes, products, or services and obtain approval for their disposition;
   - prevent the use of counterfeit parts (see 8.1.4);
   - notify CELCO of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain CELCO's approval;
   - flow down to external providers applicable requirements including customer requirements;
   - provide test specimens for design approval, inspection/verification, investigation, or auditing;
   - retain documented information, including retention periods and disposition requirements;
k) the right of access by CELCO, their customer, and regulatory authorities to the applicable

areas of facilities and to applicable documented information, at any level of the supply chain;
l) ensuring that persons are aware of:
- their contribution to product or service conformity;
- their contribution to product safety;
- the importance of ethical behavior.

CELCO ensures the adequacy of specified purchase requirements prior to communication to the vendor. The name of the purchaser is on the Purchase Order and that indicates that the purchase document was reviewed and approved.

8.5 Production and Service Provision
8.5.1 Control of Production and Service Provision
CELCO implements production and service provision under controlled conditions.

Controlled conditions include, as applicable:
a) the availability of documented information that defines:
- the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
- the results to be achieved;
b) the availability and use of suitable monitoring and measuring resources;
c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
- ensuring that documented information for monitoring and measurement activity for product acceptance includes:
- criteria for acceptance and rejection;
- where in the sequence verification operations are to be performed;
- measurement results to be retained (at a minimum an indication of acceptance or rejection);
- any specific monitoring and measurement equipment required and instructions associated with their use;
- ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).
d) the use of suitable infrastructure and environment for the operation of processes;
e) the appointment of competent persons, including any required qualification;
f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
g) the implementation of actions to prevent human error;
h) the implementation of release, delivery, and post-delivery activities;
i) the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);
j) the accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);
k) the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;
l) the determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);
m) the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;
n) the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;
o) the provision for the prevention, detection, and removal of foreign objects;

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

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

CELCO plans and carries out production in accordance with the applicable procedures and operations in sequence on the Parts Traveler For first production runs, an Estimated Routing may be issued to establish the required sequence of operations for future manufacture.

8.5.1.1 Control of Equipment, Tools, and Software Programs
Equipment, tools, and software programs used to automate, control, monitor, or measure production processes are validated prior to final release for production and are maintained.

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

Production equipment, tools and software programs used to automate and control/monitor product realization processes, are validated prior to release to production and are maintained. They are validated prior to first use and re-validated periodically according to documentation on the Parts Traveler. Validation prior to production use includes verification of the first part produced to the design.

8.5.1.2 Validation and Control of Special Processes
For processes where the resulting output cannot be verified by subsequent monitoring or measurement, CELCO establishes arrangements for these processes including, as applicable:
a) definition of criteria for the review and approval of the processes;
b) determination of conditions to maintain the approval;
c) approval of facilities and equipment;
d) qualification of persons;
e) use of specific methods and procedures for implementation and monitoring the processes;
f) requirements for documented information to be retained.

8.5.1.3 Production Process Verification
CELCO implements production process verification activities to ensure the production process is able to produce products that meet requirements.

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

CELCO retains documented information on the results of production process verification. The record is based on AS9102, current revision, for First Article Inspections.

8.5.2 Identification and Traceability
CELCO uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.
CELCO maintains the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

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

Where practical CELCO identifies the product by markings applied to the product, tag or container. During the manufacturing process the product may be identified by the Parts Traveler accompanying the 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.

Sample parts will be controlled, locked in a cabinet, in Quality. The part identification is marked on the part or the container that the part(s) are in.

CELCO identifies the product status with respect to completion of monitoring and measurement requirements, by appropriate approvals on the Parts Traveler or tag applied to product in inventory.

When stamps are used to indicate acceptance authority CELCO indicates that approved authority on the Inspection Stamp Log. All inspection stamps or acceptance media issued or unissued are to be kept in secure area when not in use and only accessible to those authorized for use to prevent unauthorized use. In order for additional personnel to be approved for acceptance authority they must be approved by management currently approved to perform this function. Refer to the Authority Matrix. No stamp or inspection media may be re-issued for a period of at least one-year after that media has been cancelled or revoked.

Where traceability is a requirement, CELCO controls and records the unique identification of the product or lots as a quality record. According to the level of traceability required by contract, regulatory, or other established requirement, the system provides for:
a) identification to be maintained throughout the manufacture and delivery;
b) all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch;
c) for an assembly, the identity of its components and those of the next higher assembly to be traced;
d) for a given product, a sequential record (Parts Traveler) of its production (manufacture, assembly, inspection) to be retrieved.

8.5.3 Property Belonging to Customers or External Providers
CELCO exercises care with property belonging to customers or external providers while it is under CELCO's control or being used by CELCO.

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

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

The use of customer furnished material is tracked on the Parts Traveler issued for the customer's part manufacture.

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

Preservation of outputs also includes, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:
a) cleaning;
b) prevention, detection, and removal of foreign objects;
c) special handling and storage for sensitive products;

d) marking and labeling, including safety warnings and cautions;
e) shelf life control and stock rotation;
f) special handling and storage for hazardous materials.

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.

8.5.5 Post-Delivery Activities
CELCO meets requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, CELCO considers:
a) statutory and regulatory requirements;
b) the potential undesired consequences associated with its products and services;
c) the nature, use, and intended lifetime of its products and services;
d) customer requirements;
e) customer feedback;
f) collection and analysis of in-service data (e.g., performance, reliability, lessons learned);
g) control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul;
h) controls required for work undertaken external to CELCO (e.g., off-site work);
i) product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).

When problems are detected after delivery, CELCO takes appropriate action including investigation and reporting.

8.5.6 Control of Changes
CELCO reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

Persons authorized to approve production or service provision changes are identified.

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

8.6 Release of Products and Services
CELCO implements planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

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

CELCO retains documented information on the release of products and services. The documented information includes:
a) evidence of conformity with the acceptance criteria;
b) traceability to the person(s) authorizing the release.

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

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

8.7 Control of Nonconforming Outputs

8.7.1 CELCO QA take action appropriate to the effects, or potential effects, of the nonconformity. Records will be maintained.

The process for approving additional personnel to perform disposition of nonconforming product is as follows:

- Person is identified by, or recommended to, the President or the Quality Manager.
- The person is asked if they want the responsibility
- If yes, they are trained on the requirements of disposition using this Quality manual section.
- Then the person participates in disposition activities until deemed trained by the Quality Manager.
- Once the training is completed, the person's name or title is added to the Authority Matrix.

8.7.2 CELCO retains documented information that:

a) describes the nonconformity;
b) describes the actions taken;
c) describes any concessions obtained;
d) identifies the authority deciding the action in respect of the nonconformity.

9. PERFORMANCE EVALUATION

9.1 Monitoring, Measurement, Analysis, and Evaluation

9.1.1 General

CELCO determines:

a) what needs to be monitored and measured;
b) the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results;
c) when the monitoring and measuring is to be performed;
d) when the results from monitoring and measurement are to be analyzed and evaluated.

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

CELCO retains appropriate documented information as evidence of the results.

9.1.2 Customer Satisfaction

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

Information to be monitored and used for the evaluation of customer satisfaction includes, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. CELCO develops and implements plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assesses the effectiveness of the results.

9.1.3 Analysis and Evaluation

CELCO analyzes and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis are used to evaluate:

a) conformity of products and services;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the quality management system;
d) if planning has been implemented effectively;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) the need for improvements to the quality management system.

9.2 Internal Audit

9.2.1 CELCO conducts internal audits at planned intervals to provide information on whether the quality management system:

a) conforms to:
- CELCO's own requirements for its quality management system;
- the requirements of AS9100;
b) is effectively implemented and maintained.

9.2.2 CELCO:

CELCO plans, establishes, implements, and maintains an internal audit program as follows:

a) Internal Audit Schedule is available and revised as deemed necessary by management. It includes:
  ➢ the frequency (current year or otherwise),
  ➢ methods (audit form to use for the audit)
  ➢ auditors (listed with the audit they are to perform)
b) responsibilities
  ➢ MR/overall audit program, coordinate audits and corrective actions, review audits and other

responsibilities as listed following.
> Auditors/perform the audits, issue corrective action as required
c) planning requirements,
> MR determines all plans for internal audits using the schedule, revised when required
d) Reporting by the MR to management, which takes into consideration the importance of the processes concerned, changes affecting CELCO, and the results of previous audits;
e) Audit criteria and scope for each audit is noted on the schedule;
f) The MR assigns auditors and so that audits are performed with assurance of objectivity and the impartiality;
g) MR ensures that the results of the audits are reported to relevant management;
h) The MR is responsible to take appropriate correction and corrective actions without undue delay;
i) The MR maintains documented information as evidence of the implementation of the audit program and the audit results

9.3 Management Review

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

9.3.2 Management Review Inputs
The management review is planned and carried out taking into consideration:
a) the status of actions from previous management reviews;
b) changes in external and internal issues that are relevant to the quality management system;
c) information on the performance and effectiveness of the quality management system, including trends in:
1. customer satisfaction and feedback from relevant interested parties;
2. the extent to which quality objectives have been met;
3. process performance and conformity of products and services;
4. nonconformities and corrective actions;
5. monitoring and measurement results;
6. audit results;
7. the performance of external providers;
8. on-time delivery performance;
d) the adequacy of resources;
e) the effectiveness of actions taken to address risks and opportunities (see 6.1);
f) opportunities for improvement.

9.3.3 Management Review Outputs
The outputs of the management review includes decisions and actions related to:
a) opportunities for improvement;
b) any need for changes to the quality management system;
c) resource needs;
d) risks identified.

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

10. IMPROVEMENT

10.1 General
CELCO determines and selects opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These include:
  a) improving products and services to meet requirements as well as to address future needs and expectations;
  b) correcting, preventing, or reducing undesired effects;
  c) improving the performance and effectiveness of the quality management system.

10.2 Nonconformity and Corrective Action
10.2.1 When a nonconformity occurs, including from complaints, CELCO uses the following process:
  a) Management reacts to the nonconformity and, as applicable:
     - take action to control and correct it
     - deal with the consequences;
  b) evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
     - Initiating the corrective action;
     - Reviewing and analyzing the nonconformity;
     - Determining the causes of the nonconformity, including, as applicable, those related to human factors;
     - Determining if similar nonconformities exist, or could potentially occur;
     - Determining the action(s) to be taken to eliminate the root cause(s);
  c) implements any action(s) identified;
  d) reviews the effectiveness of any corrective action taken;
  e) updates risks and opportunities determined during planning, if necessary;
  f) makes changes to the quality management system, if necessary;
  g) flows down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;
  h) takes specific actions when timely and effective corrective actions are not achieved

Corrective actions are recorded on the Corrective Action form. Corrective actions are appropriate to the effects of the nonconformities encountered.

CELCO maintains documented information that defines the nonconformity and corrective action management processes. Also refer to section 8.7, Control of Nonconforming Outputs.

10.2.2 CELCO retains documented information as evidence of:
  a) the nature of the nonconformities and any subsequent actions taken;
  b) he results of any corrective action.

CELCO retains records of nonconformities.

10.3 Continual Improvement
CELCO continually improves the suitability, adequacy, and effectiveness of the quality management system.

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

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