

Cal-Tron Corp

Quality Manual

QUALITY MANUAL

Issued by: **Quality Manager**

Eff. Date:

Rev.:

Quality Systems Manual

(Documented Information)

ISO9001:2015

1 of 11 pages

**EFFECTIVE DATE: March 29, 2017
REV. H**

Prepared By: _____
President

Date: March 29, 2017

Approved by: _____
QA Manager

Date: March 29, 2017

Introduction

Cal-Tron Corporation has developed and implemented a Quality Management System (QMS) in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The QMS of Cal-Tron Corporation meets the requirements of the international standard ISO9001:2015. This system addresses the, production and assemblies of the company's products.

This manual is written to cross reference our current numbering system ISO9001:2008 to ISO9001:2015 alignment. Cal-Tron Corporation's obligation to implement the basic requirements of the referenced QMS section in relation to each procedure.

This manual describes the QMS, delineates authorities, commitments, inter-relationships, responsibilities and risk's assessments of the personnel and processes responsible for performing within the system. The manual also provides procedures or references for all activities comprising the QMS to ensure compliance to the necessary requirements of the standard ISO9001:2015.

This manual is used internally to guide the company's employees through the various requirements of the ISO9001:2015 standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our QMS to our customers and other external organizations or individuals. The manual is used to familiarize them with the inter relationships between ISO9001:2015 standards and our procedures, controls that have been implemented and to assure them that the integrity of the QMS is maintained and focused on customer satisfaction and continuous improvement, meeting our customer and regulatory and statutory requirements.

It is the policy of Cal-Tron Corporation that during all phases of manufacturing, storage and shipment that the utmost precautions shall be used to preclude any damage, whether environmental or otherwise, to our product(s). The highest standards of service, workmanship, cleanliness and handling shall be maintained at every step of the manufacturing process.

Quality Manual Distribution

All QMS documentation including this manual, procedures, forms, attachments, and work instructions will be made available to Company personnel via hard copy.

Access to this Quality Manual will be made available to Customers, Suppliers, and Statutory, Regulatory Agencies by request through hard copies and or/electronic distribution.

1. Scope

Cal-Tron Corporation is a full service plastic injection mold manufacturing company. The company offers complete service from tool production in the machine shop, to plastic injection molding and secondary operations while consistently meeting our customers and applicable statutory and regulatory requirements, by implementing continuous improvements in our products and processes.

2. Normative References

The following documents were used as reference during the preparation of the QMS:

- ISO9001:2015 International Standard
- AS9102 Aerospace (First Article Inspection requirements)

3. Terms and Definitions

This section is for definitions unique to Cal-Tron Corporation.

Contract: An accepted order from the customer.

Controlled Document: Any document requiring review and approval prior to release for use.

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

Key Characteristics: The feature of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or manufacturability.

Management – Managing Directors of the Company, the President, Vice President, Managers and Supervisors.

Management Review: A management team comprised of top management: President, Production, Purchasing, Quality Manger and Human Resource.

Organization: The organization that provides a product.

Product: The result of activities or processes (i.e., tooling, molding, or technical consulting etc.)

Risk's: An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence that can effect product/s or process' directly impacting customer, regulatory and or statutory requirements.

Supplier: Subcontractor

Customers: The recipient of a product provided by the organization.

Top Management: Managing directors of Cal-Tron Corporation

4.1 Context of the Organization

We are dedicated to continuous improvement in customer satisfaction through a commitment to excellence in the production and support of world class, high quality, cost effective plastic related tooling and parts.

Cal-Tron Corporation is committed to anticipating, meeting and exceeding its customer requirements and expectations. Cal-Tron Corporation through its periodic quality system reviews determines the suitability of its quality policy, and the effectiveness of its quality system. Cal-Tron Corporation takes all necessary measures and communicates its objectives throughout the organization to achieve its quality objectives in support of its stated quality policy outlined below.

Our core mission at Cal-Tron Corporation is to meet our customers' requirements. We endeavor to consistently provide manufactured parts, tooling and value-added service that compete in a global competitive market, culture, social and economic environments.

We strive to increase sales in injection molding, tooling and value added services across a variety of markets and be open to possibilities of new markets and services in order to remain diversified.

4.3 Scope of our QMS

We define quality as more than conformance to product specifications and seek to continually improve all aspects of our business processes and quality management systems with emphasis on improving efficiency and reducing waste. Cal-Tron Corporation integrates quality consciousness throughout all its activities to ensure total customer satisfaction. We comply with and consistently adhere to internal and regulatory and statutory requirements. Cal-Tron Corporation does not have interest parties relevant to its QMS.

This is a claimed exclusion's as the company has no contractual requirement to perform this function.

Post-delivery support (8.5.5)

Design and Development (8.3)

Service (post deliveries) (8.2.3.1 a) Note: non-conforming products (services), (post deliveries) will remain in requirement.

4.4 Cal-Tron Corporation QMS and Processes

Our business ethics are solid based upon mutual trust and integrity and focused upon continual improvement, evaluations and changes needed to assure our processes achieve their intended results. Every employee of Cal-Tron Corporation is responsible and accountable for ensuring that their objectives and performance are aligned with policies and procedures. Cal-Tron Corporation establishes, implements, maintains and

continually improves our quality management system, including our process interactions, inputs, potential risk's associated and resources needed for our processes. Cal-Tron Corporation establishes authorities to assure continuous direction to its' intended results.

5.0 Leadership and Commitment

Cal-Tron Corporation is a small, third generation, family owned business with over 65 years of experience in the field of custom injection molding. We have built our reputation through our commitment, leadership and to excellence in customer focus. We know your success depends on our performance. Our staff is dedicated to complete customer service and support. Only through our commitment to high quality products and service do we achieve our goal of your satisfaction. Even a seemingly simple component may contain unforeseen and undesirable characteristics that can affect its production, performance or business processes'. We like to work closely with our customers from the initial conception through final design. This involvement allows us the opportunity, if necessary, to make recommendations that may improve the performance of the product. From initial design to production requirements, we built our business by successfully solving injection molding problems.

Our Leadership is committed to

- Publishing and communicating our Quality Policy and Quality Objectives to our entire organization.
- This Quality Manual is written to align ISO9001:2015, cross referencing our current numbering alignment.
- Documented Procedures, work instructions, and records are referenced in this Quality Manual aligned with ISO9001:2015 and crossed referenced to our current numbering system.
- Documents, including records, identified as necessary to ensure the effective planning, operation and control of our processes
- We promote Risk based thinking to assure continuous compliance.

Cal-Tron Corporation ensures that personnel have access to QMS documentation and are aware of relevant procedures.

5.2 – 5.2.2 Cal-Tron Corporation Quality Policy / Objectives

Our QMS documentation includes:

- A documented Quality Policy that is appropriate to the purpose and organization that supports our strategic directions.
- Established quality objectives,
- Commitment to satisfy our customers' requirements and

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- Committed to continuously improve our QMS.

Cal-Tron Corporation personnel understand our Quality Policy and Objectives and they are available to all employees.

5.3 Organizations roles, responsibilities and Authorities

Cal-Tron Corporation ensures that the responsibilities, authorities for specific roles are assigned and understood within the Company.

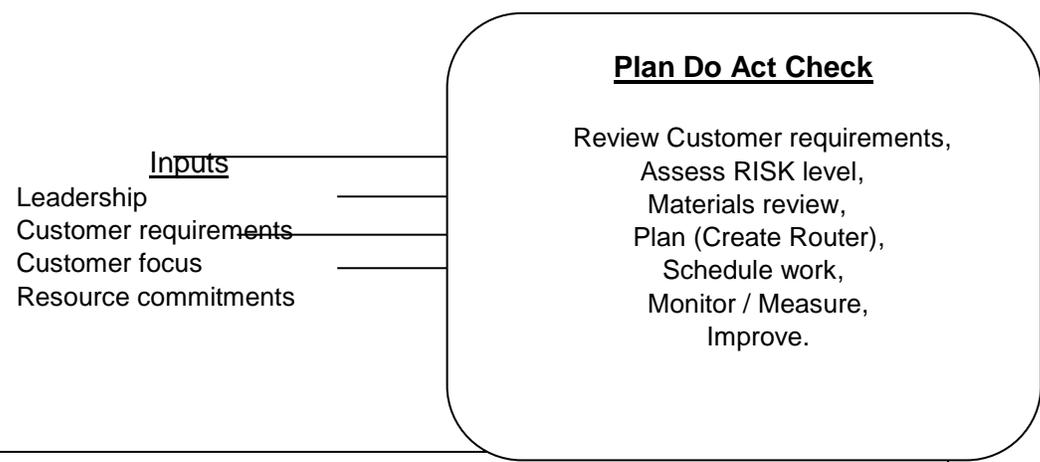
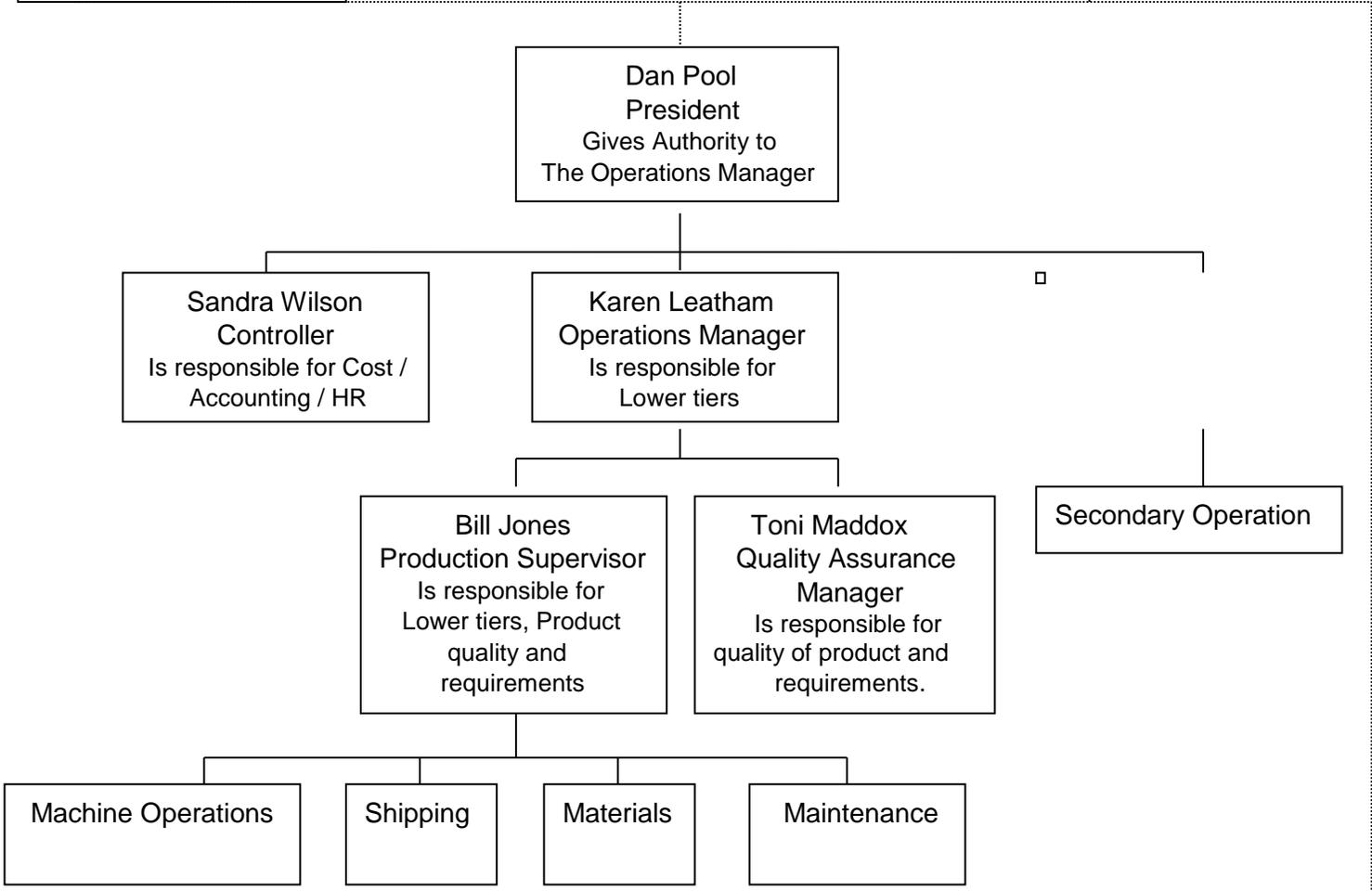
See Organizational Chart below.

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Our Team is committed in:
 Customer Focus,
 Ensuring processes are
 Delivering their indented
 Outputs.

Company Organizational

ISO9001:2015 QMS



6-6.1 Planning (actions to address risks and opportunities)

Cal-Tron Corporation takes in consideration the potential RISK's that may occur when taking on new (first time) products. Also assess repeat work for continuous improvements through the process and product's.

- a: Assures that our QMS can achieve its intended results.
- b: Improves lesser results, if warranted.
- c: Assess undesired effects/ results and actions accordingly.
- d: Asses potential RISK's that may occur and actions accordingly and evaluate the effectiveness of these actions taken.

6.2 Quality Objectives and Planning to achieve them

(Our objectives will be explained how, what and who will measure)

Cal Tron Corporation establishes Quality Objectives at specific areas of its processes. These objectives are consistent to our quality policy. These objectives will be in a measurable numeric value, which will be communicated to our management and lower tier employees.

6.3 The Operations Manager in conjunction with other mangers assists in deciding / making changes to our QMS.

A: When deciding/making changes, we take in consideration the consequences related to the process', the impact to integrity of the QMS, the availability of resources to support these changes and allocating the responsibilities and authorities with our new changes.

7-7.1 Support / Resources

Cal-Tron Corporation determines the resources required to support our process' and Company establishment, to effectively maintain a sound quality Management system through continuous improvements and by meeting our customers' requirements.

A: We take in consideration the following variables: The capabilities of and constraints of external resources and what needs to be obtained from them.

7.1.2 Our Employees

Cal-Tron Corporation determines the employees necessary to support the processes and to achieve conformity to requirements of products and services.

7.1.3 Cal Tron Corporation Infrastructure

We maintain infrastructure of our building and operations of our processes such as: equipment, building safety, software and our IT systems.

7.1.4 Environment for the operation of processes

Cal-Tron Corporation utilizes a company code of ethics in our company Employee Handbook.

Documented Information / Interactions of our processes

7.1.5 Monitoring and Measurement resources

Ref Documented information (QP 5.6 / QP 7.1 / 8.2.4)

7.1.5.2 Measurement Traceability

Ref Documented information (QP 7.6)

7.1.6 Organization Knowledge / 7.2 Competence / 7.3 Awareness / 7.4 Communications.

Ref Documented Information (QP 6.0 -6.2)

7.5 Documented information / 7.5.2 Creating and updating / 7.5.3 Control of Documented Information

Ref Documented information (QP 4.2.3)

8 Operations (Planning)

Ref Documented information (QP 7.1)

8.2 Requirements for products and Services / 8.2.2 Determining the Requirements for products and services / 8.2.3 Review Requirements for Products and services / 8.2.4 Changes to Requirements for products and services.

Ref Documented Information (QP 7.2.2)

8.4 Control of external Processes and Products / 8.4.1 Type and extent of Control / 8.4.3 Information for external providers.

Ref Documented Information (QP 7.4)

8.5 Control of Production

Ref Documented Information (QP 7.1 / 7.5)

8.5.2 Identification and Traceability

Ref Documented Information (QP 7.1 / 7.5)

8.5.3 Property belonging to customers or external providers

Ref Documented Information (QP 7.4)

8.5.4 Preservation of product

Ref Documented Information (QP 7.5.5)

8.5.5 Post-delivery Activities

Cal-Tron Corporation meets requirements such as:

- a. Customer Feed Back
- b. Non conforming product returns
- c. Statutory and regulatory requirements

8.5.6 Control of changes

Cal-Tron Corporation Operations Manager authorizes / controls all process and product changes through signing, revision and or date control.

8.6 Release of products

Ref Documented Information (QP 7.1 / 8.2.4)

8.7-8.7.2 Control of Non-Conforming out puts

Ref Documented Information (QP 8.3)

9-9.1.3 Performance evaluations, Customer Satisfaction Analysis and Evaluation

Ref Documented Information (QP 5.6)

9.2 Internal Audits

Ref Documented Information (QP 8.2.2)

9.3.2 Management review inputs

Ref Documented Information (QP 5.6)

10 Improvements

Ref Documented Information (QP 5.6)

10.2 Nonconformity and Corrective Action

Ref Documented Information (QP 8.3, QP 8.5.3)

10.3 Continuous Improvement

Cal-Tron Corporation's QMS policy is based on continuous improvement, it is shared, communicated and practiced throughout the company.

11.0 REVISIONS TO MANUAL

PURPOSE:

To maintain the current revision status of this manual, which accurately reflects the actual Quality Assurance methods, procedures and functions presently used by Cal-Tron Corporation.

REV. DATE	REVISION	DESCRIPTION
May 30, 2104	G	ISO9001:2008
March 29, 2017	H	Re-Write towards ISO9001:2015

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