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Quality Manual

Engineering Value through Quality and Innovation

Suburban Manufacturing, Inc. proudly incorporates its Quality Manual into its company website. SMI encourages comments from its customers, suppliers, employees and friends.

All hard copies of this manual are considered "uncontrolled".

To verify the current revision level of the Quality Manual, you must check www.gosuburban.com.

INTRODUCTION

Suburban Manufacturing, Inc. designs, manufactures, and distributes compressed air filtration, automatic lubrication systems, and hydraulic hose protection products along with contract manufactured components and assemblies for the Industrial, Agricultural, Automotive, Medical, and Defense Industries.

This manual is an overview of the documented quality management system that is in place at Suburban Manufacturing Inc. Management is committed to the principles of ISO 9001:2008 and to the objectives and policies needed for continuous improvement.

The quality management system is designed to establish controls throughout the entire manufacturing process from sales proposals to customer acceptance. The Quality Program complies with all requirements of ISO 9001:2008, and may comply with other government and industry standards as applicable.

Customers, suppliers, management and employees of Suburban shall use this quality manual as the primary reference point for understanding the quality system. In addition, there are work instructions and quality related forms that are part of the system. These documents describe how a process or requirement is performed. All personnel receive training in regard to these procedures and Suburban's overall quality program.

Table of Contents

Section 1: Scope

1.1 **General:**

1.1.1 **Commitment to ISO 9001:2008**. Suburban is committed to the principles and structure of ISO 9001:2008 registration. The quality manual outlines the policies, procedures and requirements of Suburban's Quality Management system. The following processes and operations are performed at Suburban Manufacturing and would fall under this control:

1.1.1.1 Business Functions: purchasing, estimating, engineering, design, quality, sales, production control/scheduling, shipping, accounting, and human resources.

1.1.1.2 Metalworking: turning, milling, and sawing.

1.1.1.3 Soft Goods: sewing, slitting, ultrasonic welding, grometting, assembly.

1.1.1.4 Assembly: both our own product and contract assembly for customers.

1.1.2 This manual will be revised and added to as necessary to reflect changes in quality requirements.

1.1.3 The management of Suburban has played an active role in the development of this QMS and supports the policies described in the manual. All employees play a vital role in maintaining and supporting quality and the QMS.

1.1.4 The QMS in place at Suburban ensures that all employees, temporary employees, and contract employees have an understanding of both the company and customer quality requirements.

1.1.5 Our Quality Manual, procedures, and work instructions are maintained electronically. Any hard copies are considered "uncontrolled."

1.1.6 Customers are encouraged to provide feedback at any time about the service, quality, delivery, and performance of any Suburban product. A contact form is provided on our website for fast, convenient communication. Suburban will continue to solicit customer feedback utilizing direct customer contact, e-tools, and social media in order to determine the health of the company.

1.2 **Application**

1.2.1 Suburban Manufacturing, Inc. has determined that the following requirements are not applicable to the operations and are documented as exclusions:

1.2.1.1 Service Provision.

Section 2: Normative Reference

2.0 Quality Management System References: The following documents were used as reference during the preparation of the Quality Management system.

2.0.1 American National Standard ANSI/ISO/ASQ Q9001-2008, Quality Management Systems – Requirements.
2.0.2 Perry Johnson Registers PRO-3, Registration Mark Procedure, Revision 9.6

Section 3: Terms and Definitions

3.0 Quality Management System Definitions. This section defines terms that are unique to Suburban Manufacturing, Inc.

3.0.1 Customer Owned Property: Any type of instrumentation, accessory, tooling, manual, or shipping container that belongs to the customer.
3.0.2 Customer supplied material: Any type of raw material product supplied to be used in the manufacture, modification, or repair of customer owned property.
3.0.3 Product: The end result of meeting all contractual terms and conditions.
3.0.4 Quality Records: Documentation of those activities wherein records must be maintained.
3.0.5 The Quality Management System is also referred to as QMS.
3.0.6 Suburban Manufacturing, Inc. is also referred to as Suburban or SMI.
3.0.7 RGA refers to the Returned Goods Authorization form.
3.0.8 ASQC: American Society for Quality Control
3.0.9 SNAFU (Suburban Non-conforming Activity Follow Up) internal form-Obsolete. Replaced with CAPA form.
3.0.10 PIF refers to a Process Improvement Form.
3.0.11 AIF refers to an obsolete Assembly Improvement form. This has been replaced by a PIF.
3.0.12 Revision refers to print revision, print version, and form version. "Version" is the terminology used within the vault process. They are both mechanisms for tracking changes made to prints and forms.
3.0.13 Master file refers to both the electronic server files and the vault system files.
3.0.14 CAPA – Corrective Action Preventive Action form – external and internal.
3.0.15 Consigned Material refers to Vendor Owned material. Also referred to as customer or supplier managed material.
3.0.16 ECO: Engineering Change Order
3.0.17 RMA: Returned Material Authorization

Section 4: Quality Management Systems

4.1 General Requirements.

Suburban Manufacturing, Inc. has established, documented and implemented a Quality Management system in accordance with the requirements of ISO 9001:2008. The system is maintained and continually improved through the use of quality objectives, internal and external audit results, analysis of data, corrective and preventative action, and management review. To design and implement the quality system, Suburban Manufacturing, Inc. has:

4.1.1 Identified the processes needed for the QMS and their applications throughout the organization. These are documented on the Process Interaction diagram at the end of this section.

4.1.2 Identified the sequence and interaction of these processes, and illustrated them on the Process Interaction diagram.

4.1.3 Determined criteria and methods needed to ensure the operation and control of the processes are effective. These are documented through the manufacturing software structure and data analysis.

4.1.4 Secured the continuing availability of resources and information necessary to achieve planned results and for the continual improvement of these processes.

4.1.5 Established systems to monitor measure and analyze the processes.

4.1.6 Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes.

4.2 Documentation Requirements.

4.2.1 Suburban Manufacturing, Inc.'s documentation includes:

4.2.1.1 Suburban's Quality policy and quality objectives.

4.2.1.2 The Quality manual, providing a general overview of the QMS, is in place at Suburban. Policies and procedures are referenced in this manual. There is no paper copy showing all documents and their revision status. All critical documentation is kept on the computer server network.

4.2.1.3 Operational, Departmental Procedures and records. Departmental activities and records that affect other departments or procedures common to the organization.

4.2.1.4 Forms and Work Instructions: Specific instructions describing in detail how a task or process is performed. These are maintained within our computer software program or on the company's intranet site.

4.2.1.5 Various quality related forms and records including, but not limited to:

- blueprints
- inspection instructions
- test procedures
- work instructions
- procedural forms
- route sheets
- standard operating procedures
- quality manual
- inspection documentation and records
- audit documentation and records
- calibration data
- quality cost documentation and records
- purchasing documentation and records
- subcontractor records
- ISO registration documentation (Perry Johnson Logo Usage)
- assembly instructions
- installation instructions

4.2.2 **Quality Manual.**

4.2.2.1 The Quality Manual has been prepared to describe Suburban Manufacturing, Inc.'s Quality Management System. The scope and permissible exclusions are described in section one of this manual.

4.2.2.2 Each section references documented QMS procedures relating to the requirements of that section.

4.2.2.3 The Process Interaction Diagram at the end of section four provides a description of the interaction between the processes of the QMS system.

4.2.3 **Control of Documents.** Quality system documentation is controlled by the use of documented procedures. Document control extends to electronic documents that affect product quality. Controlled documents, current revisions and/or current versions are maintained on the SMI network.

4.2.3.1 **Authorization and Approval:** All management representatives have the responsibility for quality documentation approval, review and control. When appropriate, department managers or leads will assist in this responsibility. The quality department, engineering department and department leads shall insure that all manuals, procedures, work instructions and specifications required are correct. The SMI's computer system keeps records of acceptance, revisions, versions, review and approval.

4.2.3.2 **Review and Update Changes to Quality:** A process improvement form (PIF) can be generated by any employee whenever an improvement in quality, process, or documentation can be achieved. This form is submitted to the PIF team, which meets on a scheduled basis to review and process the PIF's. Copies of the

completed PIF forms are stored in the part master folder, and a copy is handed back to the initiator of the PIF.

4.2.3.3 **Verification of Changes:** All documentation changes are verified by a management representative. All revision changes made to blueprints or process prints follow the ECO process.

4.2.3.3.1 **Emergency Changes:** The department manager, department lead, engineer, or quality personnel can make changes by writing the changes on any production related form. The authorized person making the change must initial and date the change on all copies of the documentation affected. Upon completion of the job, engineering, production or quality will review the changes. The master file will be reviewed and possibly updated.

4.2.3.4 **Identification of active or obsolete documents:** Obsolete quality system documents are controlled in an obsolete folder within the part master folder or in the version history within the vault.

4.2.3.4.1 Blueprint, process print control: All paper copies are uncontrolled. Production personnel are responsible to verify part number and revision levels match job process.

4.2.3.4.2 All controlled prints will be placed in the master file on the SMI network and labeled by part number and revision or part number and version.

4.2.3.4.3 All obsolete process and blue prints are placed in the obsolete folder within the part master file or in version history within the vault system.

4.2.3.4.4 The Management Team is responsible for the upkeep of the master file and vault system. The master file, vault, or Epicor may contain:

1. Master print
2. Manufacturing print
3. Archive documents
4. Production, labor, and material records
5. CAD data
6. CMM data
7. Scanned copies of previous jobs
8. Engineering information
9. Installation instructions
10. PIF’s
11. Obsolete master prints or previous versions in history

4.2.3.5 **Availability of Use**: The customer service department, production coordinator, engineering, quality department or department lead shall issue the correct revision or version of any production related information. All employees have access to the company’s intranet site to view certain production related forms and procedures.

4.2.3.6 **Legibility and Identification of documents:** Quality system documents and records are retained on the SMI Network to ensure clarity. Blue prints or process prints that are difficult to read may be replaced or redrawn, then re-approved through the appropriate workflow.

4.2.3.7 **External quality documents:** The quality department is responsible for monitoring all external documents. When required, a copy of the external document will be ordered and kept on file with the specific revision and issue date information. The external document will be tracked on our calibration system to issue current revisions.

4.2.4 **Control of Records**. The identification, collection, indexing, access, filing, storing and disposition of quality records are documented procedures. Quality records are maintained to demonstrate conformance to requirements and to provide an audit trail. A vast majority of our quality records are contained on our computer system and no hard-copies exist.

4.2.4.1 **Examples of quality and related records** include:

4.2.4.1.1 Receiving Records (Packing slips, material certifications, process certifications)

4.2.4.1.2 Design & Engineering Reviews (ECO, New Part Process Form, Advanced Deviation Requests, Deviation requests)

4.2.4.1.3 Supplier Performance & Audit Reports (Supplier RGA's, Supplier Audits, supplier communications specific to a job)

4.2.4.1.4 Inspection and Testing (Inspection Reports, SPC data, First Article results)

4.2.4.2 **Maintenance of quality and related records**.

4.2.4.2.1 All quality records are indexed.

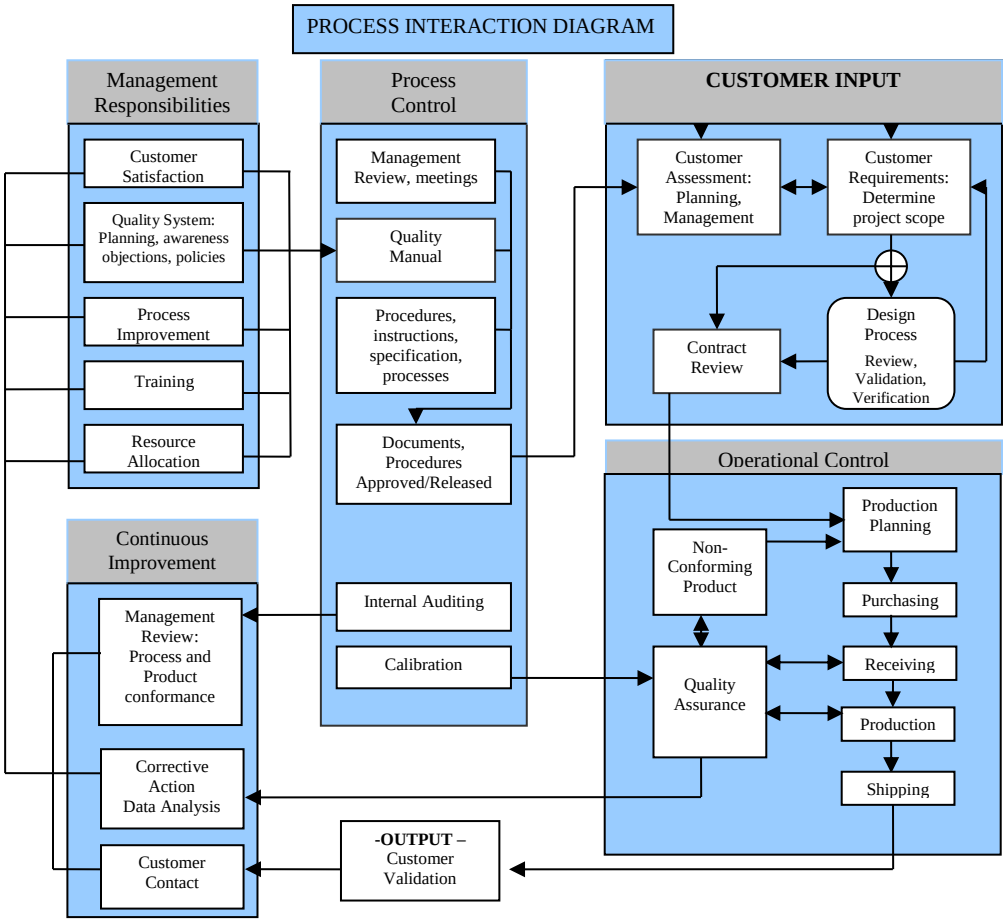
4.2.4.2.2 Quality records are stored and maintained in a suitable environment.

4.2.4.2.3 Quality records are readily retrievable.

4.2.4.2.4 When contractually required, quality records are available for evaluation by the customer or its representative.

4.2.4.3 **Disposition**: Quality and related records are retained for a minimum of three (3) years. Quality and related records may be purged after expiration of the retention period and disposed of via normal means (trash), unless otherwise directed by the customer.

4.2.5 **Process Interaction Diagram**



Rev 01: 3-24-14

Section 5: Management Responsibility

5.1 **Management Commitment.**

The CFO has overall responsibility for the QMS. Top management has been actively involved in implementing the quality system, establishing the quality policy, and quality objectives. Management has provided the vision, strategic direction, and resources necessary for the continuous improvement of the QMS and the company.

5.1.1 To continue to provide leadership and show commitment to the improvement of the QMS, management conducts employee training sessions, management review meetings, customer analysis, and annually budgets for quality related expenses.

5.2 **Customer Focus**.

All employees at Suburban Manufacturing, Inc. strive to identify current and future customer needs and requirements. Policies are in place to ensure customer requirements are understood and met through training, software, sales order related acknowledgements, job reviews, and sales analysis. Suburban Manufacturing, Inc. aims to enhance our customer's overall approval by providing new products, improving access directly to decisions makers, reviewing customer surveys and direct communication.

5.3 **Quality Policy:**

Management ensures that the quality policy is communicated to all employees. It is included in the new employee training and reinforced during company training sessions. Suburban's policy, **Engineering Value through Quality and Innovation,** explains our belief that we will gain customers based on the quality and value we offer, but we will retain customers based on our innovation or our ability to continuously improve.

5.4 **Planning:**

5.4.1 **Quality Objectives** have been established to continually improve the QMS as a whole as well as each management process, extending to processes involved with meeting product requirements. Quality objectives are measured and reviewed against performance goals during production and management review meetings and reported on the Monthly Key Process Indicator report.

5.4.2 **Quality Management System Planning**: Our quality plans are consistent with our normal methods of operation covered by existing procedures. These plans ensure that quality objectives set forth in this manual, in section 4.1 of the ISO 9001:2008 standard, and identified during management review meetings are met.

5.5 **Responsibility, Authority, and Communication**

5.5.1 **Responsibility and Authority.** An organizational chart has been established to show the interrelations of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions on the organizational chart. The organizational chart is shown at the end of this section.

5.5.2 **Management Representation.** The CFO has overall responsibility for the QMS. The Quality Manager has been appointed the management representative responsible for implementation and monitoring compliance to ISO 9001:2008. The quality manager is

responsible for reporting to the CFO any need for improvement. Further, the quality manager will promote awareness of customer requirements throughout the company via quality related records and/or through individual or company meetings.

5.5.3 **Internal Communication.** Processes are established for communication within the organization. Methods of communicating include use of the Quality manual, production meetings, company training, management review meetings, internal audits, processes improvement forms, internal emails, and other routine business communications.

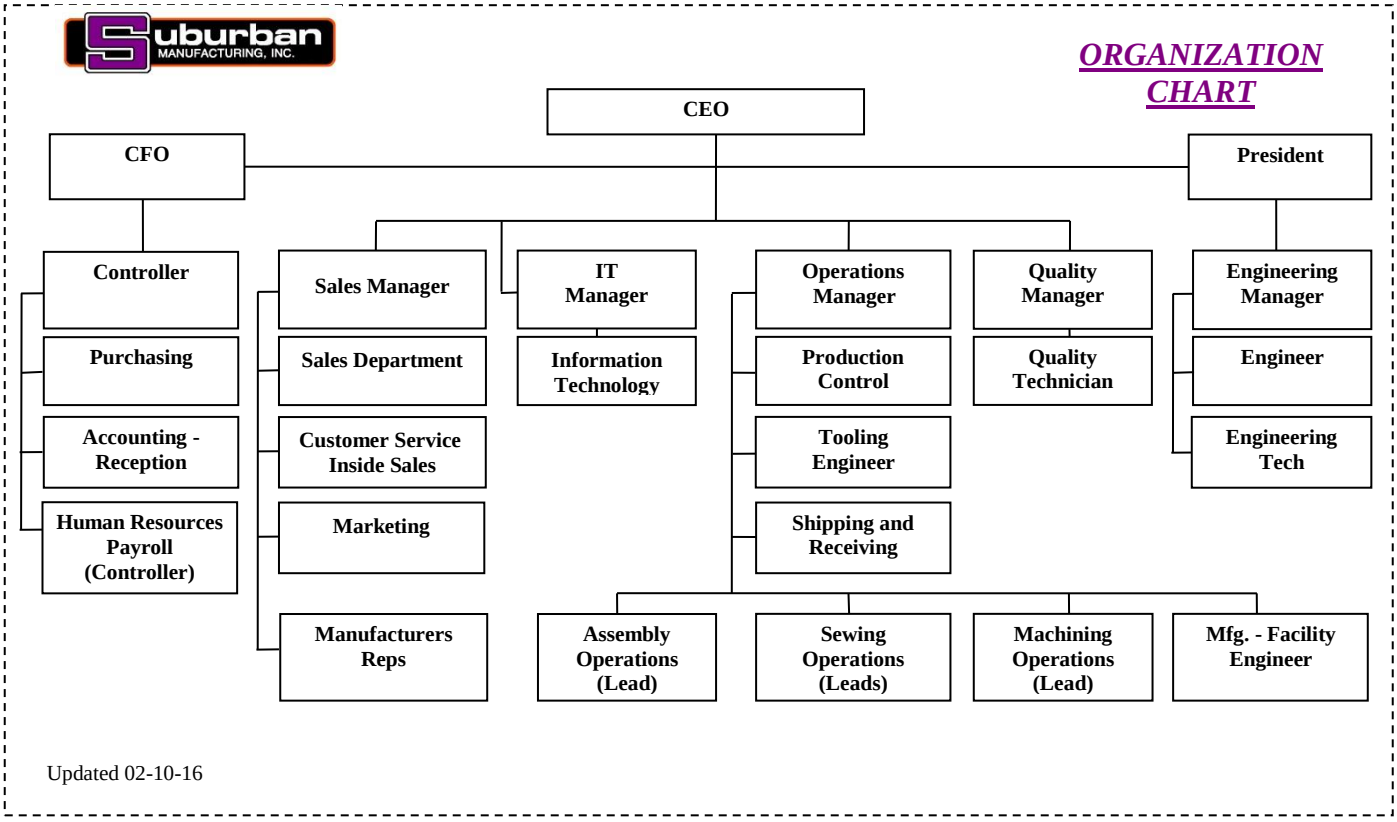
5.6 **Management Review.**

5.6.1 **General**. The President, CEO, CFO, Quality Manager, and Department managers meet on a quarterly basis to review the status of the QMS. Each section of the quality manual is reviewed for suitability and effectiveness annually based on Key Process Indicators and/or internal audits. Any management team member may coordinate management and departmental reviews and document corrective action requirements. Minutes of these meetings will be kept for a minimum of three years.

5.6.2 **Review Input:** The management review meeting is conducted using the results from various business analytics. The management review meeting agenda covers all of the topics that must be addressed during each meeting.

5.6.3 **Review Output:** During the Management review meeting, the management team will identify actions regarding the improvement of the QMS, improvement of product in relation to customer requirements, and the resources necessary to implement these improvements. These improvements will be documented on a process improvement form or through the management review action items listed on the management review meeting minutes. If there is a non-conformity discovered during the meeting, a CAPA will be initiated.

5.6.4 **Suburban Manufacturing, Inc.'s Organizational Chart**.



Section 6: Resource Management

6.1 Provision of Resources.

Suburban Manufacturing, Inc. has implemented a QMS that compiles with the ISO 9001:2008 standards. This implementation was achieved with management commitment and with sufficient resources for the implementation. Resources needed to maintain or improve the QMS are identified and appropriated through management review meetings, periodic business meetings, and daily business communications between management and staff.

6.1.1 Resources are allocated by management when required to satisfy processing requirements and produce conformance to requirements such that customer satisfaction and the quality system are not put at risk.

6.2 Human Resources.

6.2.1 **General.** To ensure competence of our personnel, job descriptions have been prepared identifying the qualifications required for each position that affects product quality. Qualifications include requirements for education, skills, training, and experience.

6.2.2 **Competence, awareness, and training**. The development of people is the primary concern of the company. It is the policy of SMI to provide adequate training to all personnel to enable them to meet the requirements of the current Quality Management System.

6.2.2.1 **Qualification:** Personnel are qualified on the basis of relevant education, training, or experience. Qualifications can be documented by performance, through documentation of prior training, current educational classes, and/or through previous job experience.

6.2.2.2 **Training methods:** The Department Manager and/or Human resource manager is responsible for determining the method of training and time frame required for an employee to achieve a necessary competence.

6.2.2.2.1 Class Room: Conducted in a classroom environment.

6.2.2.2.2 Lecture: Conducted in a more relaxed setting.

6.2.2.2.3 On the job: Training is conducted on the job. A manager or other qualified individual supervises on-the-job training.

6.2.2.3 **Certification:** Management shall identify areas where certification of personnel is required. Department Managers shall provide for the certification of personnel in specialized skills. Human Resources and/or Epicor shall maintain a record of all certified personnel and implement a re-certification program as required.

6.2.2.4 **Training:** Department managers, Department Leads, Quality and/or Human Resources personnel shall identify training needs and provide necessary training for all personnel whose work affects quality. All personnel in the organization, including new employees, shall receive training in:

6.2.2.4.1 Company Orientation

6.2.2.4.2 Initial safety review

6.2.2.4.3 ISO-9001/2008 Standards include information on Suburban's Mission Statement and Quality Manual.

6.2.2.4.4 Procedures common to all departments

6.2.2.4.5 Instructions relevant for performing specific job duties.

6.2.2.4.6 Statistical Process Control (SPC) training (if required).

6.2.2.5 **Verification**

6.2.2.5.1 A Training Matrix of required training will be completed and kept on file for each employee whose work may affect quality.

6.2.2.5.2 A record of training and previous experience for each employee shall be maintained by the Human Resource Manager and/or Epicor.

6.2.2.6 **Validation**

6.2.2.6.1 Performance reviews are used to review and discuss employee competency. Managers and employees will review on the job implementation of training.

6.2.2.6.2 Daily paperwork, quality and efficiency reports will be used to measure the results of job-specific training.

6.2.2.6.3 Internal quality audits and/or customer surveys will be reviewed to determine training effectiveness and potential areas for improvement.

6.2.2.6.4 Post training evaluation forms may be used as a means to evaluate the effectiveness of a training class.

6.3 Infrastructure.

Suburban Manufacturing, Inc. has determined and provided the infrastructure needed to meet quality objectives and product requirements. The infrastructure includes the building, production space, production equipment, assembly areas, tooling, storage rooms, workstations, utilities, process equipment, computer systems and support services. Preventive maintenance records are kept for major product equipment items. Consideration of additional infrastructure is discussed during production meetings and budgeting sessions.

6.4 Work Environment.

A work environment suitable for achieving product conformance is maintained by Suburban Manufacturing, Inc. Management ensures that the appropriate human and physical factors of the work environment are provided. Consideration of such factors includes health and safety concerns, work methods, handling methods, and ambient working conditions. All employees are encouraged to suggest improvements in the work environment. These improvements are submitted and reviewed on a process improvement form.

Section 7: Product realization

7.1 Planning of Product realization.

Quality planning is done at the earliest possible stage to ensure SMI's ability to satisfy specified requirements. It is SMI's policy to take all necessary measures to assure our customers' requirements can be met and those requirements are communicated effectively throughout the company. Quality planning may take place as a design project, through contract development, estimating, during contract review and/or during order entry.

7.2 Customer-Related Processes.

7.2.1 **Determination of requirements related to the product**. During the inquiry, quotation, and order acceptance stages of customer contact, sales personnel shall provide pertinent information regarding product requirements and customer expectations. This information includes, but is not limited to:

7.2.1.1 Types of services the customer requires.

7.2.1.2 Quantity of the customer's product requiring those services.

7.2.1.3 The customer's desired schedule for each service required.

7.2.1.4 Communicating special requirements for packaging, shipping, or handling.

7.2.2 **Review of requirements related to products**. Prior to submission of a quote or acceptance of an order, the Sales or Order Entry procedure requires that a formal review take place to ensure the Customer's requirements for the product have been clearly defined and documented. Such review also ensures that Suburban has the ability to meet the requirements.

7.2.2.1 Suburban will notify the customer of any requirements that are not understood or cannot be met.

7.2.2.2 Manufacturing challenges will be brought to the attention of the customer whenever quality requirements or delivery dates cannot be met.

7.2.2.3 Differences are resolved prior to acceptance of the order. Advance deviations are used to facilitate this process. Issues that cannot be resolved are not entered into the computer system.

7.2.2.4 Quotes do expire. Prices will be reviewed prior to job acceptance.

7.2.2.5 Change orders are reviewed against the original order. Any changes that require amendments to process or product documentation will result in revising the affected documents and notifying all affected personnel.

7.2.3 **Customer Communication**. The engineer, salesperson or quality manager will inform and/or work with the customer to resolve any discrepancies or inability of SMI to complete any of the customer's requirements. Other parties at Suburban may be involved in this negotiation process or to help with technical questions or other specific reasons. Customer Service and Sales personnel will solicit customer feedback through appropriate means.

7.3 **Design and Development.**

7.3.1 **Design and Development Planning:** In order to ensure the contracted requirements are met, it is our policy to maintain control of the design of the products we make and to verify that design. There are three basic types of design activities preformed at SMI:

- Modification of an existing design
- Reverse-Engineering products (samples provided by customers with no prints available)
- Full design service and/or design of a proprietary product.

7.3.1.1 To effectively coordinate the design effort, it is our policy to have plans that identify the responsibility for each design and development activity, as well as to use plans to describe or reference activities. These plans are updated as the design evolves.

7.3.1.2 In order to ensure the design, verification, and validation activities are done correctly, those activities are planned and assigned to qualified staff equipped with adequate resources. The plan can be developed by using checklists, flow charts, resource requirements, charts, schedules, time and cost considerations, but must follow Suburban's overall product development processes.

7.3.1.2.1 Reference SMI's Product Development Process Flowchart at the end of this section.

7.3.1.3 **Activity Assignments**: The engineering manager, engineers and estimators have direct responsibility for the planning, implementation, communication, documenting, maintaining controls, and design changes. The engineering manager is responsible for the certification, training, or educational needs of engineers and estimators engaged in implementation and maintenance of the design plans.

7.3.1.4 **Organizational and Technical Interaction**: The engineering manager is responsible for updating Suburban departments of potential projects and design changes that may impact their area. The project engineer and/or a member of the customer service or sales team are responsible for communicating with customers. The project engineer and/or purchasing department are responsible for communicating with suppliers. Acceptable methods of communication include email, telephone calls, in-person conversations or company meetings.

7.3.2 **Design and Development Input**: In order to avoid confusion about the inputs to the design and to ensure complete understanding of what the customer wants, it is our policy to identify the design scope, determine the design process through all necessary means, and review the project relative to the performance specifications or outcomes requirements for adequacy of the design. It is our policy to resolve incomplete, ambiguous, and/or conflicting requirements at the earliest possible stage.

7.3.3 **Design and Development Output**: In order to ensure the design meets the customer requirements, it is our policy to document our design output and express it in terms of requirements, quotes, blueprints, technical drawings, bills of material, manufacturing processes, notes, prototypes, calculations, and/or analysis. It is also our policy that design output:

7.3.3.1 Meets the design input requirements

7.3.3.2 Contains or references acceptance criteria

7.3.3.3 Conforms to appropriate safety and regulatory requirements whether or not these have been stated in the input information

7.3.3.4 Identifies those characteristics of the design that are crucial to the safe and proper functioning of the product

7.3.4 **Design and Development Review**: The design output is reviewed prior to release to insure conformance with expected requirements. Any issues will be identified and necessary actions addressed.

7.3.5 **Design and Development Verification**: In order to avoid incomplete verification of our design, it is our policy to plan, establish, document, and assign to qualified personnel functions for verifying that design. Verification is accomplished by means of design control measures such as:

7.3.5.1 Holding and recording design review meetings with other SMI personnel and/or the customer

7.3.5.2 Undertaking qualification tests and demonstrations including using prototypes in field applications, life cycle tests, simulation of the equipment in operation

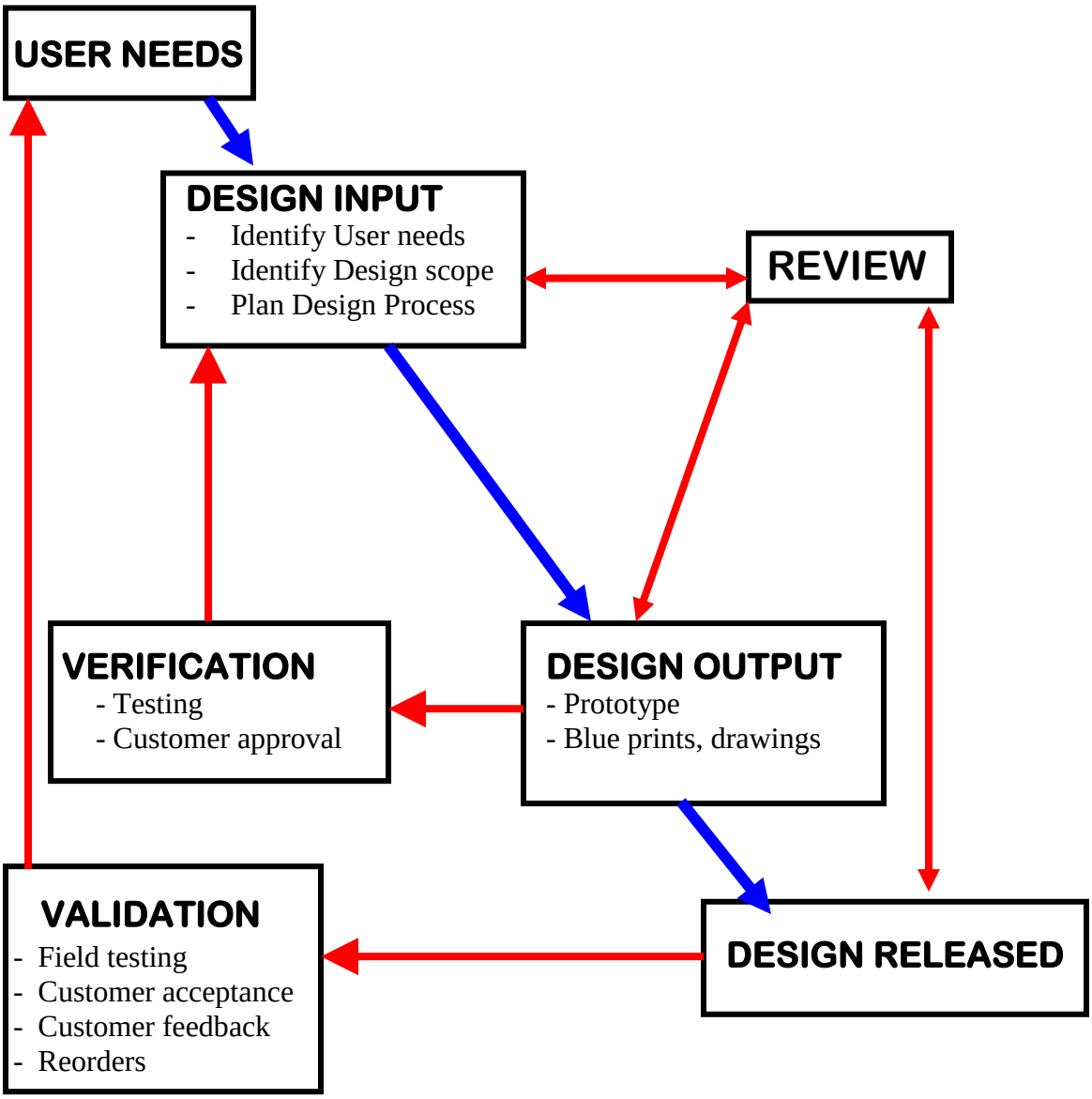
7.3.5.3 Carrying out alternative calculations

7.3.5.4 Comparing the new design with a similar proven design, if available.

7.3.6 **Design and Development Validation**: Design validation shall be performed under the customers defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual use conditions. Design validation shall also be determined through customer sign off, field testing results, customer acceptance of prints and/or design changes, customer correspondence and reorders.

7.3.7 **Design Changes**: In order to avoid unauthorized, unnecessary, or incorrect changes and modifications to the design of our product, as well as to avoid the risk of losing track and control of changes, it is our policy to have design changes and modifications identified, documented, and reviewed and approved. This shall be controlled through the ECO process, the computer system audit logs, change orders, revision numbers and/or part numbers.

PRODUCT DEVELOPMENT PROCESS



7.4 **Purchasing.**

7.4.1 **Purchasing Process:** Materials and services that have been purchased from vendors shall conform to specified requirements to ensure appropriate levels of quality, value, and service are received. Quality shall be assured by establishing procedures that will provide for controlled and effective purchasing activities by the various departments. Purchasing authority shall be assigned to personnel in various departments of the company. It shall be the responsibility of all qualified purchasing agents to communicate clear, complete purchasing documents, specifications and drawings to our vendors

7.4.1.1 **Evaluation of Vendors**: All potential vendors shall be evaluated as to their ability to comply consistently with quality requirements. Selected performance records are maintained when deemed necessary. These records include: delivery, quality, over ship/under ship, etc. Where appropriate, supplier quality systems are evaluated and documented. Vendors that are active in our computer system are considered "approved". Vendors are added/inactivated/unapproved based on the needs of SMI and that vendors past performance. When the use of an unapproved vendor is necessary to generate a quote, the vendor may be listed as "Unapproved Quoting Vendor". Details will be written on the quote. A new vendor packet or conditional use instructions (as specified by customer or contract) will be entered on the quote at this time.

7.4.1.2 There are two categories of vendors when considering what level of qualification should be imposed by the Quality System:

7.4.1.2.1 Vendors who supply sub contract products or services defined on the route sheet or identified by manufactured to print shall be subject to the formal Vendor Audit Questionnaire and approval.

7.4.1.2.2 Vendors who supply products or services not defined in the route sheet or who perform specialty services, including processes and services used under limited and exceptional circumstances are not subject to the formal vendor qualifications controls stated in this element.

7.4.1.3 The first step for any new vendor supplying a product or service used directly in the manufacture of product is the completion of a Vendor Audit Questionnaire. This questionnaire is packaged as part of a Prospective Vendor Kit. This kit consists of, but is not limited to:

A. The Vendor Audit Questionnaire (filled out and returned by vendor)

B. A copy of the SMI Standard Practices Manual

C. IRS form W-9 (filled out and returned by vendor)

D. Minnesota Certificate of Exemption (filled out by Suburban for Minnesota Vendors only)

7.4.1.4 Specialty Vendors: Specialty services include processes and services used under limited and / or exceptional circumstances.

7.4.1.5 The responses to the new vendor questionnaire are evaluated by the Quality Manager and presented at the next Management Review meeting. Vendors who have passed the initial stage of review are added to the computerized vendor database and are considered "approved". Being on the vendor database does not

guarantee work. The question of which processes each vendor has been approved for has been addressed, and compliance has been established in Epicor. For material purchases, an approved or preferred vendor is listed at the part level. For sub contract purchases, an approved or preferred vendor is listed in the method of manufacturing. If an alternate source is required, it is the responsibility of the purchasing person to validate the capability of the vendor.

7.4.1.6 Review of existing vendor performance: Vendor performance data is reviewed through the RGA system and discussed at management review meetings. Vendors which have declining performance shall be subject to re-evaluation by the Quality Manager or management representative. If there are no signs of declining performance based on RGA's or returns, no further action is required.

7.4.2 **Purchase Orders / Purchasing Information:** Vendors are provided with all required data that is pertinent to the item or service requested. Information regarding the quality system to be used and/or inspection requirements is clearly defined prior to or at the issuance of the purchase order. This information is contained in our Standard Practice Manual. Purchasing documents for outside operations and treatments are reviewed by a quality or management representative. That representative will stamp and sign/date a copy of P.O. for outside operations and treatments. Supplies, raw materials and ancillary material purchase orders are reviewed by the buyer.

7.4.2.1 Purchasing documents shall contain all applicable requirements, purchased from an approved supplier, and contain receiving inspection requirements, when appropriate.

7.4.2.2 The Quality department, Sales, Engineer, Purchasing Agent or Customer requirements determine the selection of vendors. The nature and extent of control shall depend on the type of product being procured and the vendors demonstrated ability to meet all requirements.

7.4.2.3 Assessment of vendor performance shall be consistent with the type of product or service provided.

7.4.2.4 The vendors shall be notified of special requirements such as first article, statistical process control, material certifications and special tests required.

7.4.2.5 Purchasing data provided to vendors shall include the following if applicable:

7.4.2.5.1 The type, class, grade, revision level or other clear description of the product or service ordered.

7.4.2.5.2 Inspection and test requirements.

7.4.2.6 Perishable tooling, research and development products, maintenance, shop or office supplies are not subject to these quality system requirements.

7.4.2.7 The purchasing agent shall release the purchase order to the vendor with the information specified by the requisition form, route sheet or purchasing suggestion.

7.4.2.8 In the event of blueprint or specification change, the purchasing agent shall issue a purchase order change.

7.4.2.9 When required by the customer to purchase materials or services from vendors that are not on the approved vendor list and/or have not been audited, the vendor will be granted conditional acceptance, based on contractual requirements by the customer.

7.4.2.10 All purchase orders are maintained within Epicor.

7.4.3 **Receiving Inspection / Verification**: Procedures are in place to ensure that incoming material and outside services comply with purchase order requirements.

7.4.3.1 All parts and materials subject to receiving inspection shall be inspected in accordance with customer purchase order requirements and/or single sampling plan. Inspection may be performed at either Suburban's or the vendor's facility.

7.4.3.2 The receiving inspector shall perform all necessary inspections and tests to insure conformance to requirements.

7.4.3.3 The Quality Department is responsible for maintaining receiving inspection records. These records include but are not limited to Receiving inspection records, Vendor quality records, and Rejected Material Reports

7.4.3.4 Receiving inspection may be omitted, or skip-lot, if the vendor has been established as a "dock to stock" vendor, or as required by the customer.

7.4.3.5 Upon acceptance, the inspector or quality representative shall complete and attach the move tag or material ID tag and forward the parts to the next operation.

7.4.3.6 If at any time parts or materials are rejected, the individual rejecting the material shall initiate a RGA and identify the suspect parts with a Non-conforming Material Tag.

7.4.3.7 The copy of the RGA is sent to the vendor or customer. The items in questions will be quarantined.

7.4.3.8 All non-conforming materials shall remain in the holding area until disposition, within size limitations.

7.4.3.9 Upon acceptance, the vendor supplied packing list or Suburban's miscellaneous receiving form will be used to receive the products into Epicor. The vendor supplied packing list will be maintained by Suburban's accounting department for a minimum of three years.

7.5 Production and Service Provision

7.5.1 **Control of Production and Service Provision.** All manufacturing processes are planned and carried out under controlled conditions through the use of job packets. The process control procedures are based on prevention of defects, rather than detection based on inspection results. Documented procedures are in place to ensure processes are carried out under controlled conditions. Manufacturing processes are verified, monitored and audited.

7.5.1.1 Appropriate work instructions, workmanship standards, and sales pick lists have been developed for processes that affect quality. These documents explain how to manufacture and/or assemble the product, the standard time required, what machines and/or tools should be used, and what inspection techniques need to be

employed to ensure product conformance, how the products should be packaged, and when and by whom the products should be delivered.

7.5.1.2 The majority of material is purchased for a specific job or inventory without expiration. If a product or materials expires, First-In-First-Out requirements are handled as they arise. Materials which would fall under this requirement will be coded with the date received and issued in a FIFO manner.

7.5.1.3 **Special Processes:** When required, documented instructions and training of personnel are in place for special processes.

7.5.1.3.1 **Validation of special processes:** Suburban Manufacturing, Inc. does not currently perform any special processes. However, should we develop processes and incorporate them into our manufacturing facility; the processes will be monitored and controlled via the Special Process Schedule.

7.5.1.4 **Service Provision.** Suburban does not currently perform service work.

7.5.2 **Validation of Processes for Production**. Production processes are qualified by a history of successful use. Should new or changed production processes become part of the quality management system, such processes will be qualified by management prior to their implementation. Such planning will be conducted in accordance with Management review procedures.

7.5.2.1 Currently, SMI does not use processes where the resulting output cannot be verified by subsequent measurement, outside evaluation, or monitoring. If such processes are to be included in the realization process, they will be validated prior to use to demonstrate the processes equipment and personnel, as well as defining the work instructions, procedures, required quality and related records, and the re-validation process.

7.5.3 **Identification and Traceability**. Procedures are established for providing identification of the product throughout the production cycle. Components and materials used in manufacturing shall be positively identified, marked, and verified to meet all applicable requirements. Special consideration will be given to products with limited shelf life. The process shall determine the extent and scope of inspection required and controls needed, based on the items importance and performance factors. The Quality department is responsible for performing the necessary inspection to ensure that all materials are in conformance with applicable standards and specifications.

7.5.3.1 **Identification.** Material and components intended for use in SMI's products are identified by the use of the Material tags, Move Cards, scrap or non-conforming tags, OK-to-ship Tags, Dock to Stock tags, Ok for Outside Service tags, or in the case of multiple containers of parts – written on the container or box or an additional piece of paper with the Part Number and/or Job Number and Quantity listed. This identification is maintained from receipt throughout the production cycle and delivery to the customer. Product and material stored or warehoused must be clearly identified.

7.5.3.1.1 All individual bins of material traveling throughout various processes in the manufacturing area shall have a form of identification.

7.5.3.2 **Traceability**. When contractually required traceability requirements are established to ensure conformance with customer, internal and regulatory requirements.

7.5.3.3 **Receiving Quality Records**: The Quality Department is responsible for the selection, identification and collection of all receiving inspection records necessary to monitor vendor performance and for establishing product traceability. All material certifications, certificate of conformance, first article, in process inspection sheets, test results and SPC data provided by the vendor as required shall be retained by the SMI network for a minimum of three years.

7.5.3.4 **Material Control and Traceability**: Materials used in manufacturing will be identified. Identification examples include Material ID tags, Move tags, Dock to Stock tags, Ok to Ship tags, Ok for Outside Services, Vendor ID tags or markings. Receiving personnel are responsible for ensuring the materials are identified and controlled. Receiving personnel shall maintain traceability of materials by following procedures for receiving and identifying parts and materials.

7.5.3.5 **Raw Material Control**: Raw materials that have been identified shall be released for manufacturing. Identification examples include Material ID tags, Move tags, Dock to Stock tags, Ok to Ship tags, Ok for Outside Services, Vendor ID tags or markings. Material that has no identification CAN NOT be used for production work.

7.5.3.6 **Lot Control**. The Production Count Sheet will be issued for each machining release or as required by the process. If necessary, a production lot can be run concurrently during the manufacturing process. A duplicate Production Count Sheet will be available at each concurrent work center. The originals are placed with the lead lot and the copies are placed with the lot of parts that is to be split from the original batch. The entire job packet is scanned with the final acceptance in the Quality Department.

7.5.3.7 **Tamper proof seals**. The Quality Department is responsible for the identification, calibration, affixing, and removal of tamper proof seals, and record keeping of all devices that require special precautions to guard against unauthorized adjustment.

7.5.3.8 **Outside Testing**. The Quality Manager may use outside testing or calibration services by approved subcontractors, subcontractors with measurement standards that are certified and traceable to the National Institute of Standards and Technology, or as contractually required by the customer or process. When required, the Quality Manager shall obtain customer approval to use outside calibration or testing services.

7.5.4 **Customer Property.** Customer-supplied materials will be handled using the same controls as mandated for SMI's own materials.

7.5.4.1 All raw material supplied by a customer, such as bar and flat stock, will carry identification tags tying them to a specific customer. These tags can be similar to our standard inventory tags, with the exception of the words "CUSTOMER SUPPLIED" marked on them and the name of the customer listed or be marked with customer supplied identification.

7.5.4.2 All castings, pre-cut shapes, and sawed blanks supplied by a customer will be handled in one of two ways: 1) If the blanks arrive in our facility in the customers containers and those containers contain the customers identification, Suburban will use the customers identification and will not generate a new material tag. Or 2) If the blanks arrive and are packaged in a way that does not absolutely identify the origin and part number of the material, this material will have a Customer Supplied Material Tag generated.

7.5.4.3 All unused raw material (bars, flats) upon completion of the job shall be sent back to the customer, if requested.

7.5.4.4 Unless otherwise specified, ALL castings, pre-cut shapes, and sawed blanks will be processed, regardless of the quantity stated on the customer purchase order.

7.5.4.5 Overages/Underage shall be in accordance with that customers policy with the exception stated above.

7.5.4.6 Suburban requests a 3% overage of customer supplied materials, unless specified by the customer in writing. If there are special requirements concerning this policy, they must be addressed prior to the start of any job.

7.5.4.7 Because it is assumed that material will only be provided for specific jobs, the FIFO policy does not apply.

7.5.5 **Preservation of Product**. Material is protected, maintained for handling, storage, packaging, and delivery according to documented procedures. All fabricated parts and finished products shall be handled in a manner that provides protection from damage and ensures that customer requirements are satisfied. The final product verification shall be conducted prior to shipping product to the customer.

7.5.5.1 Quality personnel shall monitor the handling of product and material to assure that practices are commensurate with the sensitivity of the products being handled and storage areas are adequate to prevent damage or deterioration.

7.5.5.2 All employees who contact parts are responsible for ensuring that all materials are properly marked, packaged, transported and stored and that applicable documents are sent with the product.

7.5.5.3 Shipping product to outside vendors for processing: Prior to shipping any product, parts, materials or assemblies to subcontractors for processing, shipping personnel, purchasing, engineering, or a quality representative shall insure the required information is listed on the purchase order or included with the shipment (as applicable).

7.5.5.3.1 The type, class, style or grade of processing required.

7.5.5.3.2 The appropriate drawing is included.

7.5.5.3.3 The specification and relevant technical data is included.

7.5.5.3.4 The inspection requirements are defined and included, as necessary.

7.5.5.3.5 The quantity of material being shipped.

7.5.5.4 Shipping of Completed Products: The following material handling and product identification steps shall be taken prior to shipping completed products. These

steps are intended to provide sufficient protection from handling related damage and to ensure accurate product identification.

7.5.5.4.1 Parts and assemblies shall be packaged to prevent deterioration.

7.5.5.4.2 The product or container shall be clearly identified.

7.5.5.4.3 Shipping shall process orders only when all required certifications, test reports and quality requirements are complete per SMI and customer requirements. This may be designed by an "OK to SHIP" tag or through removal of the stock from inventory.

7.5.5.4.4 If any discrepancies or damage is found, shipping shall contact the quality department.

7.5.5.4.5 Upon satisfactory verification, shipping shall package all materials in a manner to ensure product protection from handling and environmental damage.

7.5.5.4.6 Shipping shall comply with size and weight requirements as set by individual carriers and as specified by the customer.

7.6 **Control of Monitoring and Measuring Devices**.

7.6.1 **Documented procedures** have been developed to control inspection, measuring, and test equipment (hardware & software) to ensure accurate measurements.

7.6.2 **Calibration Records:** Records of calibration, certifications, i.d. numbers, equipment location, etc. are documented and maintained. A current calibration certificate is available upon request.

7.6.3 **Identification:** A label, tag or serial number recorded in the calibration system is the method used to identify the instrument or equipment.

7.6.4 **Traceability**: Calibration of equipment is traceable to nationally recognized standards (NIST). Where no standard exists, the basis for calibration is documented.

7.6.5 **Environmental Conditions Inspection**, measuring and test equipment is handled, preserved and stored appropriately.

7.6.6 **Non-conformance, Corrective Action**: Suspect gages will be repaired, recalibrated, or replaced. If a suspect gage is found in production, the production lot will be screened for non-conformities.

7.6.7 **Detailed Calibration Procedures:**

7.6.7.1 All inspection equipment in the gage crib will be inspected, cleaned and oiled at predetermined intervals.

7.6.7.2 Type of Gage and Frequency Check vary with many factors, such as degree of use, sturdiness of the gage, past performance.

7.6.7.3 All frequency checks are considered maximum length.

7.6.7.4 Gages may require more frequent checks, depending upon the manufacturing process the gages are being used on.

7.6.7.5 Gage condition is recorded in the Calibration system.

7.6.7.6 The Quality Department has the responsibility of continually examining the calibration intervals assigned to the measurement devices and extending or shortening them as they deem necessary.

7.6.7.7 Working Instruments - Calibration Procedure: All dimensional working instruments are to be certified as to their accuracy upon purchase.

7.6.8 **Employee Owned Measuring Equipment**. Employee owned measurement instruments are used for reference only and not maintained on the calibration system.

7.6.9 **Measuring and Test Equipment Accuracy**: This information will be specified in the calibration procedures for each type of gage.

7.6.10 **Measurement Control.** As required, the control of measuring and test equipment shall include the following:

7.6.10.1 Documented procedures for the proper selection of measuring and test instruments that are capable of the necessary precision.

7.6.10.2 Identification of all inspection and test equipment that can affect quality.

7.6.10.3 Traceability to reference standards (NIST) of known accuracy and stability. When no known standard exists, a method of calibration shall be documented.

7.6.10.4 Customer furnished gages shall not be formally maintained and controlled on our calibration system. If non-conformity is found with a customer-supplied gage, it will be addressed with the customer.

7.6.11 **Calibration.**

7.6.11.1 The Quality department is responsible for the identification, calibration, repair, and calibration record keeping of all measuring and test equipment devices and all measurement standards.

7.6.11.2 All standards used for calibration of instruments and gages shall be calibrated by an approved standards laboratory.

7.6.11.3 All personnel and departments using measuring and test equipment have the responsibility for seeing that an item of equipment is not used when its' calibration period has expired.

7.6.11.4 Calibration status identification is accomplished through the use of a sticker applied to each item of measurement standards, measuring equipment and test equipment.

7.6.11.5 Each inspected gage or instrument used for inspection shall have a tag or decal affixed to it with the following information on it:

7.6.11.5.1 Date of calibration

7.6.11.5.2 Identification of the person performing the calibration.

7.6.11.5.3 Date of next calibration due.

7.6.11.5.4 Gage Identification number

7.6.11.6 A record of each controlled gage or instrument (gage identification number) shall be maintained by the Quality Department. Such record shall contain the following minimum information:

7.6.11.6.1 Identification traceable to the gage or instrument.

7.6.11.6.2 Calibration frequency

7.6.11.6.3 Identification of the standard to be used for the calibration

7.6.11.6.4 Date of calibration

7.6.12 **Supplier Measurement Control:** The control of measuring and test equipment is extended to all approved suppliers. If a supplier has submitted non-conforming parts to SMI, the Quality manager has the right to request all calibration history on gages used for production of said parts.

7.6.13 **Corrective Action**: All SMI personnel shall report to the Quality department any measuring equipment or instruments found to be outside the required calibration limits. The Quality Manager is responsible for evaluating the occurrence.

Section 8: Measurement, Analysis, and Improvement

8.1 General.

Statistical techniques are used throughout the company as a tool for decision making and control of processes. It is the policy of SMI to utilize modern statistical methods during all stages of planning and production when required by the customer or application. The Quality Manager administers the program. When contractually required to do so, Quality shall obtain prior approval of the customer for the statistical methods or sampling plan to be used. The use of statistical techniques are not limited to inspection but are used in Sales, Engineering, and Manufacturing.

8.1.1 **Types of Control** Statistical techniques used at SMI are, but not limited to:

8.1.1.1 Process Capability Studies

8.1.1.2 Run Charts and Control Charts

8.1.1.3 Pareto Charts

8.1.1.4 Sampling Methods

8.2 Monitoring and Measurement

8.2.1 **Customer Satisfaction**. SMI utilizes several sources to collect data about customer perception as it related to meeting customer requirements including on time delivery, customer retention, and customer warranty claims. This data is reviewed quarterly during the management review meeting and compared against performance standards.

8.2.2 **Internal Audits**. Internal audits are planned and performed under controlled conditions to verify the effectiveness of the quality system. It is the policy of SMI to require a quality system audit in order to assess the degree to which the Quality Policy and Quality System are implemented. The primary tool used to verify these requirements is the Internal Quality Audit. Dock Audits are also performed to assess the conformance of outgoing product. The results of internal audits are documented and reviewed with the personnel having responsibility in the area being audited and during management review meetings.

8.2.2.1 **Dock Audits** are conducted on a monthly basis to assess the compliance of outgoing product. One packaged product is chosen at random and compared to stated customer specifications. The Dock Audit form controls what needs to be inspected and verified. The dock audit form also contains a flow chart to guide every employee on what to do if a non-conformity is found.

8.2.2.2 **A review audit** will be conducted annually and submitted to the CFO for review and approval. This audit will verify that all internal audits were conducted during the past 12 months, and that all sections of the quality manual have been reviewed.

8.2.2.3 **Auditor Qualification**. Only qualified personnel are allowed to conduct the required internal audits. Each audit must have at least one lead auditor. Audit team members and audit team observers are optional.

8.2.2.3.1 Lead Auditor: Completed the requirements and awarded an ISO-Based lead auditor certificate **(or)** must have practical experience of 5 or

more documented audits as an audit team member and have approval from the quality manger.

8.2.2.3.2 Audit Team Member: Must have practical experience of 3 or more documented audits as an audit team observer and exposure to in-house training.

8.2.2.3.3 Audit Team Observer: none

8.2.2.4 **Auditor Training** Suburban has two options for training internal auditors. In-house training and utilizing outside sources for training. Both methods are acceptable for proper training.

8.2.2.4.1 Option 1: In-house Training. The Quality Manager will approve an in-house auditor training program. The in-house training program shall (at the minimum) consist of Reference materials on auditing and an understanding of how SMI relates to the ISO 9001:2008 standards.

8.2.2.4.2 Option 2: Outside sources. Training provided by sources outside the company that are approved by the Quality Manager can be substituted for internal training.

8.2.2.4.3 Records of achievement: Human Resources and/or Epicor are responsible for maintaining the records of auditor training and certification.

8.2.2.5 **Audit Procedure**: The Auditor is responsible for; scheduling the audit, gathering the data, conducting the analysis, and writing a report detailing the results of the audit. Audit worksheets are available to add structure. If a non-conformance is identified, a CAPA is generated based on the findings. If a preventative action or process improvement is identified, a PIF is generated based on the findings.

8.2.2.5.1 Audit Worksheet. This document is used as a guide to help conduct the audit and ensure all requirements for conducting internal audits have been met. This worksheet is not meant to be read or used as a checklist.

8.2.2.5.2 Outside Auditors: Outside auditors are allowed to complete internal audits as well as use their own forms for documenting results and analysis. If an outside auditor finds a non-conformity, a CAPA will be initiated to correct the issue. All other findings such as; observations, concerns, and preventive action recommendations will be reviewed with the management team and the course of action will be determined at that point.

8.2.2.6 **Audit Results**: All quality records, audit forms, and audit results will be maintained as per section 4.2.4.

8.2.3 **Monitoring and Measurement of Processes**. SMI has implemented methods for monitoring and, where applicable, measuring the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. These results are discussed during the management review. When the results are not achieved, and a cause is not determined, a CAPA is generated and corrective action is taken as to

ensure product conformity. Key Process Indicators, Internal audits and management review are a few of the methods used to monitor the process.

8.2.4 **Monitoring and Measurement of Products**. SMI has implemented methods for monitoring and measuring the characteristics of the product to verify product requirements are fulfilled. These methods are used at appropriated stages of the product realization process. Quality and related production records are maintained throughout the process. Product is not released to the customer until all planned processes have been satisfactorily completed.

8.2.4.1 Product realization process methods includes, but is not limited to:

8.2.4.1.1 Establishment, review, and release of the work instructions and / or job packet.

8.2.4.1.2 Material Verification

8.2.4.1.3 Set up, first article, and in-process inspection.

8.2.4.1.4 Outside Processes

8.2.4.1.5 Transportation and packaging

8.2.4.1.6 Final Inspection

8.2.4.1.7 Post Production requirements and review.

8.3 **Control of nonconforming product**.

Non-conforming material and product is controlled to prevent unintended use. SMI maintains an effective system for controlling nonconforming material. Repair or rework of nonconforming material shall be according to documented approved instructions.

8.3.1 A management representative shall review all occurrences where materials or product fails to meet the specified requirements and shall take appropriate action to prevent recurrence. Reports on the number of non-conformities found are generated within Epicor.

8.3.2 **All Employees have authority to stop the process if non-conformities are detected**.

8.3.3 **All incoming material**, work in process and completed product is subject to the documented requirements for controlling non-conforming material. Procedures and work instructions are in place to control the identification, documentation, evaluation, segregation (when practical), and disposition of non-conforming materials and product.

8.3.4 **Review and Disposition**. The MRB is responsible for review and authority for the disposition of non-conforming material and product. Non-conforming material and product is reviewed and dispositioned in a controlled manner to ensure only approved material or product is released.

8.3.5 **Re-Inspection:** Material or product that is reworked or sorted will be re-inspected according to documented instructions.

8.4 **Analysis of Data**:

SMI determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. Data is presented during production meetings and

management review meetings. This includes data resulting from monitoring and measuring products, process improvements, customer satisfaction, internal on-time delivery, external on-time delivery and efficiencies.

8.5 **Improvement.**

8.5.1 **Continual Improvement.** SMI will continually improve the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, CAPA's, PIF forms (process improvements), and management review.

8.5.2 **Corrective Action.** SMI will take action to eliminate the cause of non-conformities in order to prevent reoccurrence. Actions taken are appropriate to the impact of the problems encountered. Corrective action may be initiated by anyone in the company. Such action will be documented through the use of the following: CAPA form, MRB log, RGA form, non-conforming material tags, customer corrective action forms or Process Improvement forms. Any resulting changes to processes or procedures will be reflected in the appropriate documents.

8.5.2.1 Corrective actions may arise from a variety of sources, including:

8.5.2.1.1 Internal Audits

8.5.2.1.2 Customer complaints

8.5.2.1.3 Identification of Non-conforming materials, product trends or clearly identifiable causes.

8.5.2.1.4 Rejected Goods Authorizations

8.5.2.2 **Evaluation & Analysis:** A planned and documented procedure exists for the evaluation of customer complaints, audit results, rejected in-coming material & supplies, and non-conforming reports. These findings are analyzed to determine if Corrective Action required. Use of a CAPA form and/or non-conforming material tag with "cause and corrective action" analysis may be authorized to determine root cause.

8.5.2.3 **Corrective Action**: Corrective Action is designed to prevent reoccurrence by correcting problems in the process, resolving potential problems, developing supplier relationships and other methods. All customer requests for corrective action shall be routed to the Quality Manager. The response to a CAPA is determined by the Material Review Board, Quality Manager or Department Manager.

8.5.2.4 **Methods & Controls:** Quality, with the assistance of engineering and production, shall investigate the root cause of quality problems. Where appropriate, statistical analysis and statistical process control is the preferred method of evaluating the results of corrective actions. Other controls are also used to monitor corrective and preventative actions. Corrective actions will be reviewed by representatives from Quality, Engineering and Production for comments and/or approval.

8.5.2.5 **Records**: Corrective actions are documented and records are maintained.

8.5.2.6 **Permanent Changes:** Quality and/or Engineering shall determine when permanent changes from corrective action necessitate the issuance of new or

revised work instructions, manufacturing processes, product specifications and/or change to the quality system.

8.5.3 **Preventive Action**: SMI has documented procedures to eliminate the potential non conformities in order to prevent their occurrence. The Quality department, with the concurrence of Engineering and/or Production/Operations, shall determine the appropriate degree of preventive action required based on the magnitude of the problem. The Preventative Actions will be documented on a PIF form and will be reviewed as defined by the form guidelines.

REVISION HISTORY

Revision Date	Section	Description of Change
2/10/16	Cover Page	Added the website address instead of only referring to "this website"
	Table of Contents	Fixed improper page references. Added revision history start page.
	3.0.7	Changed from rejected to returned.
	3.0.15	Added comment about vendor and supplier managed material.
	3.0.17	Added RMA.
	4.2.3.1	Removed redundant statement about issuing documentation. It was stated in 4.2.3.5.
	4.2.3.2	Updated PIF process to refer to PIF team.
	4.2.3.3	Clarified by adding revision changes to statement about the ECO process.
	4.2.3.5	Added statement about all employees having access to the company's intranet site.
	5.6.2	Reworded the review input paragraph to refer to the management review meeting agenda for a list of items to be covered during the meetings.
	5.6.3	Added statement about starting a CAPA if a non-conformity is found.
	5.6.4	Removed all personnel names from the chart. Removed CEO from the sales manager position. Added Controller to the HR position.
	6.2.2.3	Added Epicor being able to handle records of certification.
	6.2.2.5.2	Added Epicor being able to handle training records.
	8.2.2.1	Reworded the paragraph to allow the dock audit form to control the process.
	8.2.2.3	Clarified that internal audits must have a lead auditor.
	8.2.2.3.1	Removed ASQ Qualifications from requirements. Added requirement for quality manager approval.
	8.2.2.4	Clarified that there are two options for training internal auditors.

	8.2.2.4.3	Added Epicor being able to track auditor training certificates.
	8.2.2.5	Removed statement about CAPA's being closed in the management review meetings.
	8.2.2.5.2	Added section about using outside auditors to complete internal audits.
	8.2.2.6	Referenced section 4.2.4
	8.3.1	Replaced Quality manager with Epicor for generating non-conformity reports.
05/03/15	All	Revision History was moved from the second item in the manual to the last section in the manual. Revision History format was changed so that the latest revisions are shown first.
	All	Introduction Statement. Removed redundant "and", commas.
	3.0.9	SNAFU internal form became obsolete. Replaced with CAPA.
	3.0.14	Added CAPA – Corrective Action Preventive Action form
	3.0.15	Added Consigned Material definition
	3.0.16	Added ECO. Engineering Change Order.
	4.2.3.1	Change Quality Manager to Management Representatives.
	4.2.3.3	Change Revision Change Matrix to ECO. Removed CAD workflow. Removed "recall" language as it is referenced on the new ECO form.
	4.2.3.3.1	Replaced "the job route sheet, work instruction, process prints or blueprint(s)" with "any production related form." Removed "The person authorizing the change is responsible for follow up activities." Added Production to the list of departments that can review the changes. Changed "master file will be updated" to read "The master file will be reviewed and possibly updated."
	4.2.3.4.4	Updated master file location to include Epicor. Changes Quality Department to Management team. Expanded litem 4 to include labor and material records.
	4.2.3.5	Added Customer Service and Production Coordinator, and engineering to departments allowed to issue correct revision, version, process prints, and specifications.
	4.2.3.6	Change "insure" to "ensure." Change CAD workflow to appropriate workflow.
	4.2.4.1.2	Replace "Revision change matrix" with ECO and/or New Part Process form.
	5.3	Added 'ly' to continuous. Now reads "continuously."
	5.4.1	Added "and reported on the Monthly Key Process Indicators."
	5.4.1.1.1 – 5.4.1.1.7	Removed list of examples.
	5.6.1	Review of QMS now done on a quarterly basis. Change from the Quality Department may to "Any management team member may coordinate management and departmental reviews and document corrective action requirements."
	5.6.3	Change submit on a PIF to read that improvements will be documented on a PIF or through the management review action items denoted in the Management Review Meeting minutes.

6.2.2.4	Added Department leads
6.2.2.5.1	Changed “keep” to “kept.”
7.1	Changed “customer’s” to “customers’.”
7.2.2.3	Remove “Process Circumvention Form.”
7.2.3	Added “customer service” to sales. Both will solicit customer feedback.
7.3.1.4	Changed “The project engineer is responsible for communicating with customers and suppliers” to read “The project engineer and/or a member of the customer service or sales team are responsible for communicating with customers. The project engineer and/or Purchasing Department will be responsible for communicating with suppliers.”
7.3.7	Change “Revision Change Matrix” to ECO process.
7.4.1.1	Deleted “Vendors are added/removed based on the needs of SMI and that vendors past performance. Vendors which are on our computer system are considered "approved". New vendors are evaluated” and replaced it with “Vendors that are active in our computer system are considered "approved". Vendors are added/inactivated/unapproved based on the needs of SMI and that vendors past performance.”
7.4.1.3	Added “but is not limited to:” for the list.
7.4.2.7	Added “Requisition Form.”
7.4.1.5	Changed Production Meeting to Management Review Meeting. Dropped the word “raw” from the definition of materials. Redefined a place to store information about purchased materials and sub contract to, “For material purchases, an approved or preferred vendor is listed at the part level. For sub contract purchases, an approved or preferred vendor is listed in the method of manufacturing.”
7.5.3.3	Changed Quality Department to SMI network.
7.5.3.6	The Production Route sheet, etc. is now the “Entire Job Packet” will be scanned.
7.5.3.8	Added “Calibration Services.”
7.5.4.1	Removed the words “Rubber Stamped” on the ID tag. Added “or be marked with customer supplied identification.”
7.5.4.6	Replace “scrap” with “Overage.”
8.2.1	Change Bi-annual to Quarterly.
8.2.2.1	Replace SNAFU with CAPA.
8.2.3	Replace SNAFU with CAPA.
8.4	Updated Data Analysis list. Removed Sales Analysis, Indirect hours, added internal OTD, external OTD.
8.5.1	Replace SNAFU with CAPA.
8.5.2	Replace SNAFU with CAPA.
8.5.2.2	Added “to” before determine. Added Use of a “CAPA form and/or non-conforming material tag.
8.5.2.3	Replaced “The need for corrective action is determined by…” with “The response to a CAPA is determined by…”

10/07/14	5.6.2	Added "SNAFU's and Customer Corrective actions or non-conformities are reviewed and closed during management review."
3/24/14	1.1.6	Replace randomly mailed surveys with direct customer contact
	3.0.10	Removed AIF reference. All PIF are Process Improvement Forms
	3.0.11	Removed AIF reference.
	4.1.3	Removed "work procedures."
	4.2.1.5	Added Assembly instructions and Installation Instructions
	4.2.3	Added "and/or current version."
	4.2.3.1	Added "or version" and "version" to lists.
	4.2.3.2	Removed AIF reference.
	4.2.3.3	Added "or CAD workflow."
	4.2.3.4	Added "or version history within the vault system."
	4.2.3.4.2	Added "or part number and version."
	4.2.3.4.3	Added "or version history within the vault system."
	4.2.3.4.4	Added "and the vault system" to what the Quality department is responsible to maintain. Updated the list that the master file or vault master file may contain to include "manufacturing prints." Added "or previous versions in history" next to obsolete prints.
	4.2.3.5	Added "or version."
	4.2.3.6	Removed old approval process and added re-approval "through the CAD workflow.
	4.2.5	Updated Process Interaction Diagram. Replaced Customer survey with Customer Contact and added Receiving to Operational Control.
	5.1	Replaced President with CFO for overall responsibility of the QMS.
	5.4.1.1.2	Replaced Customer Satisfaction surveys with Customer Retention.
	5.4.1.1.6	Reword Core Process Matrix to "Key Process Indicator" reports
	5.4.1.1.7	Added "On-Time Deliveries"
	5.5.2	Replaced President with CFO.
	5.5.3	Deleted reference to assembly improvement form
	5.6.1	Added CFO to meeting list. Replaced "Core Process Matrix" with "Key Process Indicators."
	5.6.2	Removed the word "survey". Replaced "Core Process Matrix" with "Key Process Indicators."
	5.6.4	Updated the Organization Chart.
	6.2.2.6.1	Removed "Competency Based Training is reviewed and evaluated." Replaced with "Performance reviews are used to review and discuss employee competency."
	6.4	Removed AIF reference.

	7.3.1.2.1	Updated SMI's Product Development Process Flowchart. Removed "Satisfaction Survey's" from Validation and replaced with "Customer Feedback."
	7.5.4.2	Changed "flame-cut" to "Pre-cut."
	7.5.4.4	Changed "flame-cut" to "Pre-cut."
	8.2.1	Remove reference to "Customer Satisfaction surveys, reworded to read, "SMI utilizes several sources to collect data about customer perception as it related to meeting customer requirements including on time delivery, customer retention, and customer warranty claims. This data is reviewed bi-annual during the management review meeting and compared against performance standards."
	8.2.2.1	Change from quarterly to monthly dock audits.
	8.2.2.2	Replaced President with CFO.
	8.2.2.5	Added "The SNAFU is reviewed and closed during Management Review Meetings."
	8.5.1	Removed AIF reference.
	8.5.2	Added "customer correction action forms."
	8.5.2.1.3	Removed "or survey's."
	8.5.3	Removed AIF reference and Snafu form.
4/23/13	4.2.3	Remove "hard copy" and "master file." These are now on the SMI network.
	4.2.3.2	Copies of process improvements are retained in the quality department or on the SMI network.
	4.2.3.3.1	Add work instructions to list.
	4.2.3.4	Add obsolete documents are controlled in an obsolete folder within the part master folder.
	4.2.3.4.1	Related to blue print and Process print control: Change to "All paper copies are uncontrolled. Production personnel are responsible to verify part number and revision levels match job process.
	4.2.3.4.2	All controlled prints will be placed in the master file on the SMI network and labeled by part number and revision.
	4.2.3.4.3	All obsolete processes and blue prints are placed in the obsolete folder within the part master file.
	4.2.3.4.4.	Remove items 1 (Document control card) and 3 (2 copies of the shop print). Update 5, remove "blank." Reword to read, "The master file shall always contain the master print. All other items are optional.
	4.2.3.5	Reword Availability of Use: The quality department or department lead shall issue the correct revision, process prints, and specifications… Remove reference to transfer drive and the Cal 3 system, add quality documents are on the quality network.
	4.2.3.6	Update to "records are retained on the SMI network…" Remove master file reference. Add re-approval can also be done by the quality manager.
	4.2.3.7	Change "program" to "system."

	5.6.4	Update Suburban's organizational chart.
	7.2.3	Add quality manager.
	7.3.7	Correct wording to "controlled." Add ECO process.
	7.4.1.6	Review of existing vendors. Add "if there are no signs of declining performance based on RGA's or returns, no further action is required."
	7.5.3.6	Lot Control. "The production count sheet will be issued for each machining release or as required by the process." Remove reference to "shop" related to prints. Change "filed" to "scanned with the final acceptance in the SMI network." Changed "filed back in the master file" to discard.
	7.6.3	Change Cal3 software to calibration system.
	7.6.7.5	Change Cal3 to calibration.
	7.6.7.5.1	Remove table related to calibration procedures. The new system obsoletes these procedures.
	8.2.1	Add "or completed by customer service or sales people upon discussions with a customer."
	8.2.3	Add "the results are discussed during the management review. If the cause is not determined during the discussion, a SNAFU…"Add KPI to list.
	8.5.3	Add "AIF" to PIF.
06/30/12	1.1.3	Corrected "maintain" to "maintaining".
	1.1.4	Added "temporary employees, and contract employees"
	1.1.6	Removed reference to phone and email list on website. Added contact form and social media as a means to measure customer satisfaction.
	3.0.10	Added PIF – Process Improvement Form
	3.0.11	Added AIF – Assembly Improvement Form
	4.2.1.3	Changed record to records. Removed and.
	4.2.3.1	Added department leads can assist quality manager. Changed quality manager to quality department, engineering department and department leads shall insure paperwork and issue latest revision documents.
	4.2.3.2	Added AIF – Assembly Improvement Form. Changed Quality to the department reviewing the PIF/AIF issues updates.
	4.2.3.3.1	Added department lead can make changes. Added quality to review changes upon completion.
	4.2.3.4.2	Changed form to document control "card."
	4.2.3.4.3	Added quality department responsibility.
	4.2.3.4.4	Updated Quality manager to Quality department.
	4.2.3.5	Updated Quality manager to Quality department. Revised Vantage system to Epicor.
	4.2.3.6	Added "and Master File" for storage of quality documents.
	4.2.3.7	Updated Quality manager to Quality department.
	5.5.3	Added "assembly improvement form."
	5.6.1	Added CEO to bi-annual meeting.
	5.6.4	Updated Organizational chart, removing personnel names.

	6.2.2.1	Changed though to through.
	6.2.2.3	Change Quality manager to Department managers
	6.4	Added AIF – Assembly Improvement form.
	7.4.1.2.1	Added “or identified by manufactured to print”
	7.4.1.5	Revised Vantage to Epicor. Added “For raw material purchases, an approved or preferred vendor is listed at the part level. If an alternate source is required, it is the responsibility of the purchasing person to validate the capability of the vendor.”
	7.4.1.6	Change production meetings to Management Review Meetings.
	7.4.2	Added prior to “or at” the issuance of the purchase order.
	7.4.2.10	Revised the Vantage System to Epicor.
	7.4.3.1	Removed “in accordance with Zero-Defect Sampling plan.”
	7.4.3.7	Changed segregated to quarantined.
	7.4.3.9	Revised the Vantage System to Epicor. Changed 12 month minimum to three years for retention of vendor packing lists.
	7.5.3.1	Added “Dock to Stock tags, Ok for Outside Service tags, or written on the container or box.”
	7.5.3.3	Updated records retained for a minimum of three years.
	7.5.3.4	Added “Identification examples include Material ID tags, Move tags, Dock to Stock tags, Ok to Ship tags, Ok for Outside Services, Vendor ID tags or markings.” Removed quality personnel and replaced with receiving personnel. Removed “determine the acceptable materials.”
	7.5.3.5	Removed “If material has a yellow or white SMI material tag...through…production work. Added “Identification examples include Material ID tags, Move tags, Dock to Stock tags, Ok to Ship tags, Ok for Outside Services, Vendor ID tags or markings.”
	7.5.3.6	Changed production to “machining release or as required by the customer.” Updated to read “The Production Count Sheets and/or route sheets are filed with the final acceptance in the Quality Department. The blueprints are filed back in the Master file.”
	7.5.4.3	Replaced “Unless otherwise specified” with “if requested.”
	7.6.8	Changed employee owned tools are “for reference only and not maintained on the calibration system.”
	7.6.11.7	Removed completely. Calibration of employee’s personal tools is dealt with in section 7.6.8.
	8.2.2.3.1	Updated training requirements to ASQ recognized ISO-Based lead auditor certificate.”
	8.2.2.5	Added “or observation” for generation of a SNAFU.
	8.5.1	Added “AIF” – Assembly improvement form.
09/30/11	5.6.4	Updated Organizational chart with new personnel.
	6.2.2.6.1	Competency Based Training is reviewed and evaluated during performance reviews.

2/24/2011	5.6.2	Added "Vendor performance and/or audits" as an input point for the Management Review Meetings.
	8.5.2.	Updated to include additional forms, procedures.
	8.5.2.1.3	Updated to ID of non-conforming materials, product trends, or clearly identifiable causes.
	8.5.3	Added SNAFU form to list of Preventative Action Forms. Revised "in accordance to our procedure" to read "as defined by the form guideline."
7/30/2010	8.2.2.3.2	Removed "or was trained by lead audit" and added "and exposure to in-house training."
04/21/2010	4.2.1.2	Policies and Procedures are referenced, not linked.
	5.4.1.1.6	Add Core Process Matrix sheet
	5.6.1	Add Core Process Matrix, Reword
	5.6.2	Add Core Process Matrix.
	6.2.2.3	Change from Quality manager to Management
	6.2.2.5.1	Change checklist to Training Matrix
	7.2.2.4	Customer Process – Change to Quotes do expire.
	7.5.1.2	Production – Change wording to address only products that expire will use the FIFO method.
	7.6.8	Add "all controls of the calibration system." Grammar correction.
	8.2.2.3.1	Change ASQC to ASQ. Add ISO-9001:2000 and ISO-9000:2008
	8.2.2.1	Change from monthly to quarterly dock audits.
	8.2.2.5	Add preventative action in addition to process improvements.
	8.5.2.1.1	Remove Management Review meetings, re-number.
	8.5.3	Add the Preventive Actions will be documented on a PIF form and reviewed in accordance with our procedure.
5/08/2009	All	Updated from ISO 9001:2000 to ISO 9001:2008 format.
3/21/2008	5.6.1	Management review meetings changed to bi-annually.
	5.6.4	Updated Organizational chart with new personnel.
11/09/2007	All	Updated from ISO 9001:1994 to ISO 9001:2000 format.