Auburn Manufacturing Business Management System Manual

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Conforms to AS9100 Rev. D and ISO 9001:2015

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	Appendix A: Overall Process Sequence & Interaction

0.0 Revision History and Approval

Rev.	Nature of changes	Approval	Date
[Rev Number]	Original release.	[Quality Manual Approver Name]	[Date of Issue]
New	New Quality Management System Manual in compliance with AS9100D and ISO 9001:2015.	MC	8/1/2017
25 {D3}	Continued revision level sequencing from prior quality manual. Revised section 8.1.4, Prevention of Counterfeit Parts to reflect actual implementation of processes, in response to internal audit findings. Revised section 5.3, Organization Roles, Responsibilities and Authorities and organization chart, based on recent organization changes. Revised section 6.2, Quality Objectives based recent changes in data sourcing, measurement, interpretation, in response to internal audit findings and management review. Revised section 4.0, Context of the Organization to clarify current implementation and reformatted the interaction of processes flowchart.	GM/RC	07/06/18

1.0 Welcome to Auburn Manufacturing

Our Quality Management System documentation includes a documented Quality Policy statement, quality system requirements imposed by regulatory authorities, and quality objectives. We define our processes including those required by AS 9100 in procedures that define process inputs, outputs, and sequence of activities. Our documented procedures identify the documents needed to ensure effective planning, operation, and control of our processes. Records required by ISO, AS 9100 are identified on a Records List in accordance with the Document Control procedure. We ensure that our employees have access to and are aware of quality management system documentation. Customers and regulatory authorities have access to quality management system documentation when requested. If quality system requirements are imposed on us by a regulatory authority we include the requirement in a procedure and/or on the Green Slip Package.

The manual, procedures, and all process documentation that requires approval and/or source qualification shall be written in English.

2.0 About Auburn Manufacturing Quality Manual

This manual is prepared for the purpose of defining the company's interpretations of the AS9100 Revision D and ISO 9001:2015 international standards, as well as to demonstrate how the company complies with that standard.

Note: The AS9100D and ISO 9001 is used in reference to the latest standard noted above.

This manual presents "Notes" which are used to define how Auburn Manufacturing has tailored its management system to suit its purposes. These are intended to clarify implementation approaches and interpretations for concepts which are not otherwise clearly defined in ISO 9001 or AS9100.

3.0 Terms and Definitions

Auburn Manufacturing adopts the following terms and definitions within its Quality Management System. Where no definition is provided, the company typically adopts the definitions provided in ***ISO 9000: Quality Management – Fundamentals and Vocabulary*** and AS9100 Rev D. In some cases, specific procedures or documentation may provide a different definition to be used in the context of that document; in such cases, the definition will supersede those provided for in this Quality Manual or the referenced definition sources.

General Terminology

Auburn Manufacturing = Auburn

Document – written information used to describe how an activity is done.

Record – captured evidence of an activity having been done.

Risk-Based Thinking Terminology

Risk – Negative effect of uncertainty

Opportunity – Positive effect of uncertainty

Uncertainty - A deficiency of information related to understanding or knowledge of an event, its consequence, or likelihood. (Not to be confused with measurement uncertainty.)

Product Terminology

- **Customer Property** – Customer supplied material or product that is utilized in the manufacture, modification, or inspection of the final product.
- **Product** - The end item result of meeting all contract's terms and conditions (e.g.: manufactured goods, merchandise, services, etc.).
- **Quality Records** - Documentation of those activities wherein records of said activities must be maintained will be specified in the System Procedure or Work Instruction level documents, as applicable.
- **Material Review Board (MRB)** – Quality, Production and Management members who have complete disposition authority of discrepant product (subject to customer/government restrictions).
- **Special Requirements** - Those requirements identified by the customer, or determined by the organization, which have high risks of not being met, thus requiring their inclusion in the operational risk management process. Factors used in the determination of special requirements include product or process complexity, past experience, and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

  NOTE: Special requirements (3.5) and critical items (3.2), along with key characteristics (3.3), are interrelated. Special requirements are identified when determining and reviewing requirements related to the product (see 8.2.2 and 8.2.3). Special requirements can require the identification of critical items. Design output (see 8.3.5) can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to be controlled.
- **Quality Manual (QM)** - The top level (level 1) document, which defines the Quality Management System.
- **System Procedure (SP)** - Documented processes of the Quality Management System (level 2), which are referenced by the Quality Manual.
- **Work Instructions (WI)** - Documented processes of the Quality Management System (level 3), which are referenced by the System Procedures.
- **Flow Charts (FC)** – Document process outline of the work flow which may also be used as a work instruction
- **Risk** – An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.
- **Critical Items** – Those items (e.g., functions, parts, software, characteristics, and 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 of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.
- **Key Characteristic** – An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation.
- **Rework:** Efforts to bring nonconforming product into conformance through additional operations that do not alter the original design of the product.

- **Repair:** Efforts to bring nonconforming product into conformance through additional operations that alter the original design of the product; this may be through the addition of material no specified in the original design, or through altering pre-existing design features.
- **Scrap:** The discard of nonconforming product in lieu of reworks or repair.
- **Product Safety** - The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.
- **Counterfeit Part** - An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer.

  NOTE: Examples of a counterfeit part can include, but are not limited to, the false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics.

4.0 Context of the Organization

4.1 Understanding the Organization and Its Context

Auburn Manufacturing has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company. Auburn monitors internal and external issues that are of concern to its business and its interested parties, through inputs & outputs to and from its core processes (Contract Review, Purchasing, and Production) and its support processes, primarily management review.

STRATEGIC DIRECTION is discussed during management review.
Such issues are monitored and updated as appropriate, and discussed as part of management reviews.

4.2 Understanding the Needs and Expectations of Interested Parties

The issues determined are identified through an analysis of risks facing Auburn Manufacturing and its interested parties. “Interested parties” are those stakeholders who receive our Products or Services, or who may be impacted by them, or those parties who may otherwise have a significant interest in our company.

This information is then used by senior management to determine the company’s strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

4.3 Determining the Scope of the Quality Management System

Based on an analysis of the external and internal issues referred to in 4.1, the requirements of relevant interested parties referred to in 4.2, and in consideration of its products and services, Auburn Manufacturing has determined the scope of the management system as follows:

SCOPE: Manufacture of die-cut non-metallic materials. The distribution of non-metallic washers, shims, gaskets, and insulators.

Not Applicable:

8.3 Design & Development: Since Auburn Manufacturing works to customers' requirements and prints and does not develop or design products, Auburn has determined that the requirements of AS9100 section 8.3 are not applicable to this quality management system.

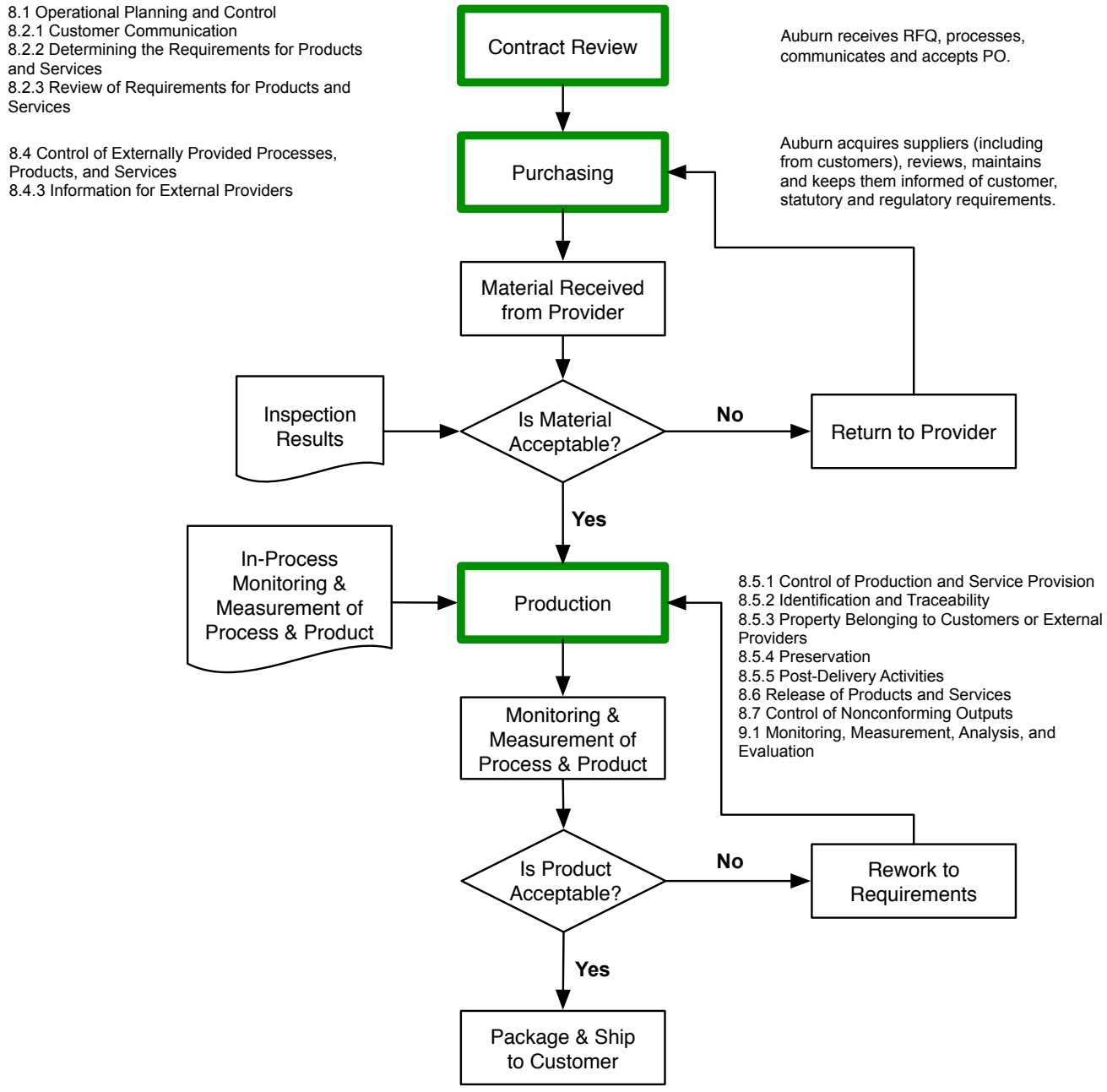
This quality management system applies to all processes, activities and employees within the company and the facility located at:

29 Stack Street
Middletown, CT 06457

A description of the interaction between the Core processes of the quality management system is posted here.

Supporting Processes for Each Process: Management Review; Internal Audit; Training; Corrective Action

"Core Processes"



4.4 Quality Management System and Its Processes

4.4.1 Auburn has established, implemented, maintained, and continually improved its quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard. *Auburn's quality management system also addresses customer and applicable statutory and regulatory quality management system requirements. See sections 1.0 and 2.0 above.*

Auburn has determined the processes needed for its quality management system and their application throughout the organization. The embedded flowchart above illustrates Auburn's interaction of processes, including how it has:

a. determined the inputs required and the outputs expected from these processes;

b. determined the sequence and interaction of these processes;

c. determined and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;

d. determined the resources needed for these processes and ensure their availability;

e. assigned the responsibilities and authorities for these processes; see also section 5.3, Organizational Roles and Responsibilities, included below;

f. addressed the risks and opportunities as determined in accordance with the requirements of 6.1; see also section 4.0, Context of the Organization, included above.

g. evaluated these processes and implement any changes needed to ensure that these processes achieve their intended results;

h. improved the processes and the quality management system.

4.4.2 To the extent necessary, the organization has:

a. maintained documented information to support the operation of its processes;

b. retained documented information to have confidence that the processes are being carried out as planned.

The organization has established and maintained documented information that includes:

- a general description of relevant interested parties (see 4.2 a);

- the scope of the quality management system, including boundaries and applicability (see 4.3);

- a description of the processes needed for the quality management system and their application throughout the organization; see embedded flowchart above and section 4.4.1.

- the sequence and interaction of these processes;

- assignment of the responsibilities and authorities for these processes.

Leadership

5.1 Leadership & Commitment

5.1.1 General

Auburn Manufacturing provides evidence of its leadership and commitment to the development and implementation of the management system and continually improving its effectiveness by:

a) taking accountability of the effectiveness of the management system;

b) ensuring that the ***Quality Policy*** and quality objectives are established for the management system and are compatible with the strategic direction and the context of the organization;

c) ensuring the integration of the management system requirements into the organization's other business processes, as deemed appropriate (see note);

d) promoting awareness of the process approach;

e) ensuring that the resources needed for the management system are available;

f) communicating the importance of effective quality management and of conforming to the management system requirements;

g) ensuring that the management system achieves its intended results; or responds when intended results are not achieved with appropriate actions.

h) engaging, directing and supporting persons to contribute to the effectiveness of the management system;

i) promoting continual improvement;

j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer focus

Management of Auburn Manufacturing adopts a customer-first approach which ensures that customer needs and expectations are determined, converted into requirements and are met with the aim of enhancing customer satisfaction.

This is accomplished by assuring:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;

b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c) the focus on enhancing customer satisfaction is maintained;

d) product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved.

5.2 Policy

5.2.1 Establishing the Quality Policy

Management at Auburn Manufacturing has developed the Quality Policy, that governs day-to-day operations to ensure quality. The Quality Policy is released as a standalone document as well, and is communicated and implemented throughout the organization.

The Auburn Manufacturing Company's Quality Policy is to provide our customers with product whose quality meets or exceeds the contracted requirements and on-time delivery so that we become their preferred choice. We are committed to continuously improving the effectiveness of our operations & improving our on-time delivery & customer satisfaction.

Quality objectives are established, monitored, measured and updated accordingly, primarily through management review, or other QMS processes; see below section 6.2, Quality Objectives.

All Auburn Manufacturing employees are aware of:

- their contribution to product or service conformity - (Everyone contributes in achieving Quality)
- their contribution to product safety – (Everyone contributes in achieving safety of product, including: FOD, shelf-life controls, storage and handling conditions)
- the importance of ethical behavior – (Everyone contributes in providing accurate and forthright information regarding the status of product – to include non-conformances).

5.2.2 Communicating the Quality Policy

The quality policy shall be available and maintained as documented information. It is also communicated, understood, and applied within the organization and available to relevant interested parties, as appropriate.

5.3 Organizational Roles Responsibilities and Authorities

Management has assigned responsibilities and authorities for all relevant roles in the company.

The Management Representative role has been assigned the Production Manager when having a single point of contact to represent the Auburn Manufacturing quality system is useful or required by customer or regulations. Auburn's Management Representative has the organizational freedom and access to top management to resolve quality management issues. The Management Representative is responsible for:

a) ensuring that the quality management system conforms to the requirements of this International Standard;

b) ensuring that the processes are delivering their intended outputs;

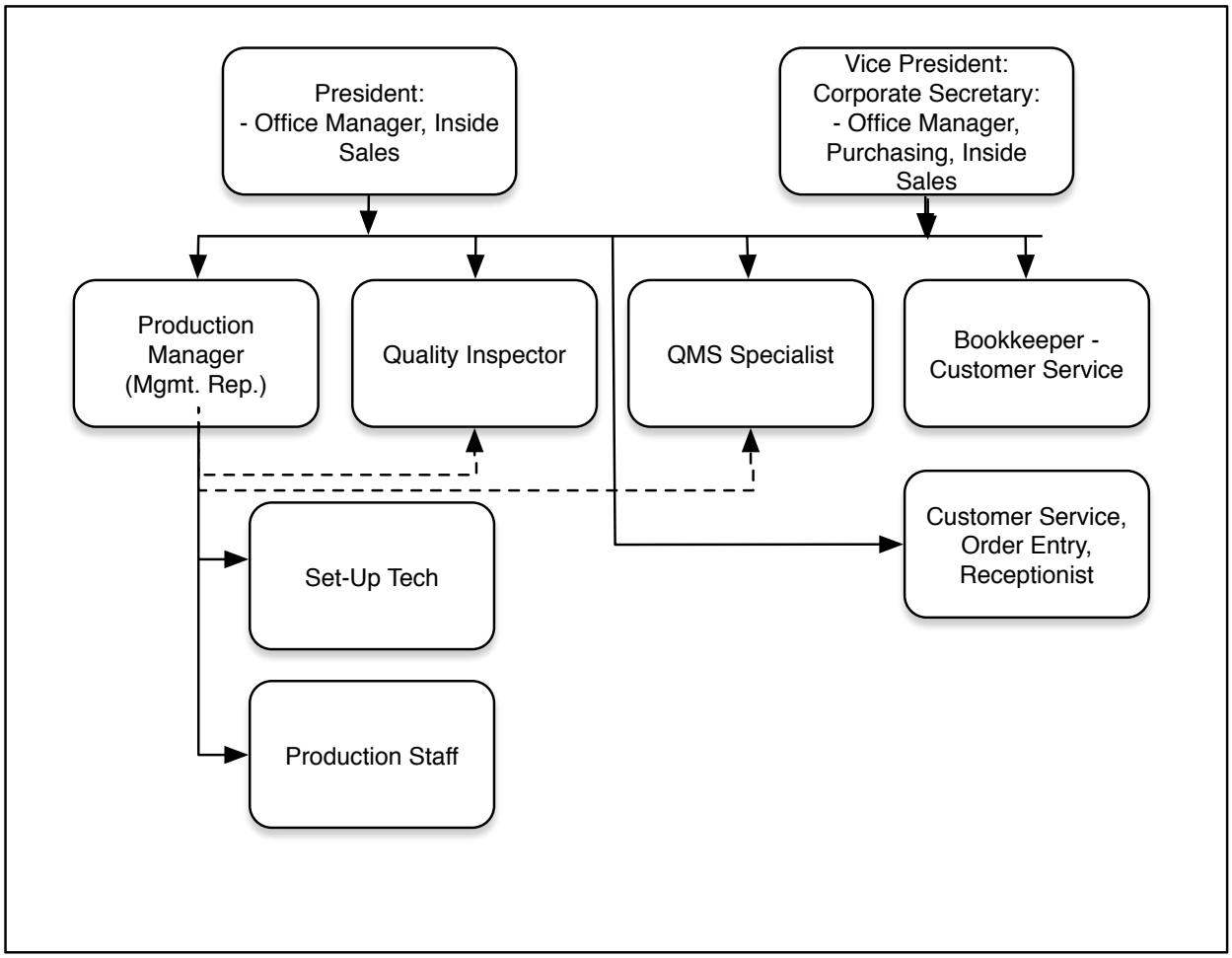
c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;

d) ensuring the promotion of customer focus throughout the organization;

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

f) delegating activities to the QMS Specialist, as needed to support the QMS implementation.

Organization Chart:



Quality Planning

6.1 Actions to Address Risks and Opportunities

Auburn Manufacturing considers risks and opportunities when taking actions within the management system, as well as when implementing or improving the management system; likewise, these are considered relative to products and services. Risks and opportunities are identified as part of the "Context of the Organization Exercise"

6.2 Quality Objectives and Planning to Achieve Them

As part of the adoption of the process approach, Auburn Manufacturing utilizes its process objectives, as the main quality objectives for the QMS. These include overall product-related quality objectives; additional product-related quality objectives are defined in work instructions, production documents or customer requirements.

Quality objectives are:

- Quality to Customer & Customer Satisfaction
  - Customer Issues w/N/C by Vendor
  - Customer Issues w/N/C by Auburn
- On-Time Delivery to Customers
- On-Time Delivery from Vendors

The process objectives have been developed in consideration that they:

a) be consistent with the quality policy;

b) be measurable;

c) take into account applicable requirements;

d) be relevant to conformity of products and services and to enhancement of customer satisfaction;

e) be monitored;

f) be communicated;

g) be updated as appropriate.

Quality objectives are established at relevant functions and levels in the organization to support our organization's efforts in achieving our quality policy and reviewed during Management Review meetings for suitability. Quality objectives are measurable, consistent, and reviewed against performance goals at each management review meeting.

6.3 Planning of Changes

The QMS has been planned and implemented by The President of Auburn Manufacturing, and the Top Management Team to meet Quality Objectives and general requirements of the AS9100 and ISO 9001 standards, as applicable. Quality planning takes place as changes that affect the QMS specified during management reviews are planned and implemented.

7.1 Resources

7.1.1 General

Auburn Manufacturing determines and provides the resources needed:

a) to implement and maintain the management system and continually improve its effectiveness

b) to enhance customer satisfaction by meeting customer requirements

Resource allocation is done with consideration of the capability and constraints on existing internal resources, as well as needs related to supplier expectations.

Resources and resource allocation are assessed during management reviews.

7.1.2 People

Senior management ensures that it provides sufficient staffing for the effective operation of the management system, as well its identified processes.

7.1.3 Infrastructure

Auburn Manufacturing determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, buildings, workspace process equipment, hardware and software, supporting services such as transport, information and communication technology.

7.1.4 Environment for the Operation of Processes

Auburn Manufacturing provides a clean, safe and well-lit working environment. Management of Auburn Manufacturing manages the work environment needed to achieve conformity to product requirements. Specific environmental requirements for products are determined during quality planning and are documented in subordinate procedures, work instructions, or production documentation.

Human factors are considered to the extent that they directly impact on the quality of Products or Services.

7.1.5 Monitoring and Measuring Resources

Where equipment is used for critical measurement activities, such as inspection and testing, these shall be subject to control and either calibration or verification.

Auburn Manufacturing has recognized the importance of the measurement and monitoring to be undertaken, and the equipment needed to provide evidence of product conformity to requirements. Where necessary, to ensure valid results, measuring equipment is:

- Calibrated or verified or both at specified intervals, or prior to use, against measurement standards traceable to the international or national standards (where no such standards exist, the basis used for calibration or verification is recorded);
- Adjusted or re-adjusted (in rare cases and as necessary);
- Identified to enable calibration status to be determined;

- Safeguarded from the adjustments that would invalidate measurement result;
- Protected from damage during handling, maintenance and storage;
- Recalled according to a defined method when requiring calibration.

Auburn Manufacturing assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements and takes appropriate actions on the equipment and any product affected. Records of the results of calibration and verification are maintained.

In addition, Auburn Manufacturing maintains a register of the Monitoring and Measuring Equipment. The process used for their calibration is defined by System Procedure 7.6. It includes details of the equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

Ability of the computer software to satisfy intended application is confirmed when used in monitoring and measurement of the specified requirements. This shall be undertaken prior to initial use and reconfirmed as necessary.

Auburn Manufacturing ensures that environmental conditions are suitable for the calibrations, inspections and measurements being carried out.

7.1.6 Organizational Knowledge

Auburn Manufacturing also determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This may include knowledge and information obtained from:

a) internal sources, such as lessons learned, feedback from subject matter experts, and/or intellectual property;

b) external sources such as standards, academia, conferences, and/or information gathered from customers or suppliers.

This knowledge shall be maintained, and made available to the extent necessary.

When addressing changing needs and trends, Auburn Manufacturing shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge.

7.2 Competence

Staff members performing work affecting product quality are competent based on appropriate education, training, skills and experience. The documented procedure defines these activities in detail.

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. Auburn Manufacturing maintains records of the employee qualifications*, and* determine the necessary competence for personnel performing work affecting conformity to product requirements*,* if any differences between employee's qualifications and the requirements for the job are found, training or other action (where applicable) is taken to achieve the necessary competence for the job. The results are then evaluated to determine if they were effective. Training and evaluation are conducted according to the Competence. Employees are trained on the relevance and

importance of their activities and how they contribute to the achievement of the Quality Objectives.

7.3 Awareness

Training and subsequent communication ensure that all personnel are aware of the:

a) the quality policy;

b) relevant quality objectives;

c) their contribution to the effectiveness of the management system, including the benefits of improved performance;

d) the implications of not conforming with the management system requirements,

e) relevant quality management system documented information and changes thereto;

f) their contribution to product or service conformity;

g) their contribution to product safety;

h) the importance of ethical behavior.

This information can be found within the skills matrix records.

7.4 Communication

Management of Auburn Manufacturing ensures internal communication takes place regarding the effectiveness of the management system. Internal communication methods include the use of corrective and preventive action processes to report nonconformities or suggestions for improvement. Use of the results of analysis of data, meetings and use of the results of the internal audit process. Communication can occur within emails, memos and / or verbal. Management does have an “open door” policy which allows any employee access to management for discussions on improving the quality management system.

7.5 Documented Information

The management system documentation includes both documents and records.

Documents required for the management system are controlled in accordance with Auburn’s Document Control procedure. The purpose of document control is to ensure that staff have access to the latest, approved information, and to restrict the use of obsolete information. All documented procedures are established, documented, implemented and maintained.

A documented procedure has been established to define the controls needed for the identification, storage, retrieval, protection, retention time, and disposition of quality records. This procedure also defines the methods for controlling records that are created by and/or retained by suppliers.

7.5.3.1 Documented information required by the quality management system and by this International Standard shall be controlled to ensure that it is available and suitable for use, where and when it is needed and that it is adequately protected (e.g., from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, Auburn Manufacturing addresses the activities, (when applicable) for the distribution, access, retrieval, use, storage and preservation, including preservation of legibility. In addition, the control of changes, retention and disposition.

The prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

8.1 Operational Planning and Control

Auburn Manufacturing plans and develops the processes needed for realization of its Products or Services. Planning of Product or Service realization is consistent with the requirements of the other processes of the management system. Such planning considers the information related to the context of the organization current resources and capabilities, as well as Product or Service requirements.

Such planning is accomplished through:

a) determining the requirements for the Products or Services.

b) establishing criteria for the processes and the acceptance of Products or Services.

c) determining the resources needed to achieve conformity to the Product or Service Sing. requirements;

d) implementing control of the processes in accordance with the criteria;

e) determining, maintaining and retaining documents and records to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate the conformity of Products or Services to their requirements;

f) determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;

g) engaging representatives of affected organization functions for operational planning and control;

h) determining the process and resources to support the use and maintenance of the Products or Services.

i) determining the products and services to be obtained from external providers;

j) establishing the controls needed to prevent the delivery of nonconforming Products or Services. to the customer.

The management team controls planned changes and reviews the consequences of any unintended changes, during management review, then acts to mitigate any adverse effects, as necessary.

Auburn Manufacturing controls outsourced processes through the purchasing process...

Due to the nature of Auburn Manufacturing's work, formal program or project management is not implemented.

Auburn's purchasing process controls the temporary or permanent transfer of work, to ensure the continuing conformity of the Products or Services; and this process provides consideration for how work transfer impacts and risks are managed, as applicable.

8.1.1 Operational Risk Management

Operational risk management is conducted to manage the risks related to Product or Service realization requirements. This includes assigning responsibility for risk management, defining risk identification, implementation, management, assessment, communication of risks and acceptance of risks remaining after implementation of mitigating actions. See above section 4.1, Context of the Organization.

8.1.2 Configuration Management

Auburn Manufacturing plans, implements, and controls configuration management activities as appropriate to its Products or Services, and per applicable customer requirements. This is done to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This includes document control for configuration documents, and change control for configured items.

1. Configuration Identification - products are controlled by the quality department and corresponding documents and records. At a minimum, Part Number and Revision of the product will be documented.
2. Configuration Change Control – This happens when a Part Number's Revision change is implemented, per applicable customer requirements.
    a. Products of different configurations will be identified and segregated, according to their corresponding Part Number and Revision Levels..
    b. Document(s) representing new configurations will be issued, according to their corresponding Part Number and Revision Levels.

8.1.3 Product Safety

Auburn Manufacturing does not design products. Therefore, operational controls have been implemented to assure product safety to the extent of meeting customer requirements, including the customer's design. However, as appropriate to Products or Services, Auburn may support customer relevant activities including:

a) assessment of hazards and management of associated risks;
b) management of safety critical items;
c) analysis and reporting of occurred events affecting safety;
d) communication of these events and training of persons.

8.1.4 Prevention of Counterfeit Parts

Auburn Manufacturing provides for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to it's aerospace customers, per customer requirements, which are determined during contract review. The primary operational controls implemented for counterfeit prevention are within the processes for purchasing and the applicable receiving inspection, and identification and traceability of materials/parts throughout all other processes.

8.2 Customer Related Processes

8.2.1 Customer Communication

Auburn Manufacturing has implemented effective communication with customers in relation to:

a) providing information relating to Products or Services.
b) handling enquiries, contracts or orders, including changes;
c) obtaining customer feedback relating to products and services, including customer complaints;
d) handling or controlling customer property;

e) establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the Requirements Related to Products and Services

During the intake of new business Auburn Manufacturing captures:

a) the requirements for the products and services, including any applicable statutory and regulatory requirements and other requirements deemed necessary by Auburn Manufacturing

b) requirements not stated by the customer but necessary for specified or intended use, where known

c) special requirements

d) operational risks (new technologies, capability and capacity, delivery time frames, etc.)

These activities are defined in greater detail in the procedure*.*

8.2.3 Review of Requirements Related to Products and Services

Once requirements are captured, Auburn Manufacturing reviews the requirements prior to its commitment to supply the Product or Service This review ensures that:

a) product requirements are defined

b) contract or order requirements differing from those previously expressed are resolved

c) the organization can meet the defined requirements, and/or the claims for the products and services it offers

d) special requirements (see 8.5.1 below) can be met

e) risks have been identified and considered

These activities are defined in greater detail in the procedure.

8.2.3.2 The organization shall retain documented information, as applicable:

a. on the results of the review;

b. on any new requirements for the products and services.

8.2.4 Changes to Requirements for Products and Services

The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and Development

EXCEPTION: Auburn Manufacturing does not perform Design and Development Operation

8.4 General Requirements

The Quality Management System (QMS) has been created in accordance with the requirements of the AS 9100 International Standards and addresses customer and applicable statutory and regulatory requirements. The system is maintained and continually improved using the Quality Policy, Quality Objectives, audit results, analysis of data, corrective and preventive actions and management reviews.

Note: Auburn Manufacturing also provides customers' or regulatory authority's access to the QMS documentation.

To design, establish and implement the Quality Management System Auburn Manufacturing has:

- Determined processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the Quality Manual.
- Determined the sequence and interaction of these processes, and illustrated them on the Process Flow Diagram.
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective, and documented them in the System Procedures, Quality Plans, Work Instructions, etc.
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes.
- Established system to measure, (*where applicable*), monitor and analyze these processes.
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes.
- In choosing to outsource a process that affects product conformity Auburn Manufacturing will ensure control over such processes. The type and extent of control to be applied to these outsourced processes is defined within the QMS.
- NOTE:1 Processes needed for the Quality Management System referred to above include processes for management activities, provisions of resources, product realization, measurement, analysis, and improvement.
- NOTE: *2*. An outsourced process is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.
- NOTE: 3. Ensuring control over outsourced processes does not absolve the organization of responsibility of conformance to all customer, statutory, and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as:
- The potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements.

- The degree to which the control for the process is shared.
- The capability of achieving the necessary control through the application of Clause 7.4

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 Purchasing Function

At Auburn Manufacturing the Purchasing Process and Documentation System Procedure is to control its purchasing function to ensure that the purchased product conforms to requirement. Suppliers are selected against defined criteria and are subject to planned review and evaluation. Some of the criteria are: on time delivery, quality and meeting specific requirements. The results of evaluation and follow up actions are recorded. Approved suppliers will be reviewed during Management Review Meetings and at the Monthly Management Meeting.

Note: Auburn Manufacturing is responsible for conformity of all product purchased from suppliers including customer designated sources**.**

Auburn Manufacturing will:

- The organization shall be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.
- The organization shall ensure, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.
- The organization shall identify and manage the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers.
- The organization shall require that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.

8.4.1.1 The organization shall

- maintain a register of its suppliers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family),
- Periodically review supplier's performance (records of these reviews shall be used as a basis for establishing level of controls to be implemented);
- Define necessary actions to take when dealing with suppliers that do not meet requirements;
- Ensure where required that both the organization and all suppliers use customer approved special process sources;
- Ensure that the function having responsibility for approving supplier quality system has the authority to disapprove the use of sources.

- define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on the supplier's approval status, and

8.4.2 Purchasing Function

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

When external provider test reports are utilized to verify externally provided products, the organization shall implement a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or organization has identified raw material as a significant operational risk (e.g., critical items), the organization shall implement a process to validate the accuracy of test reports.

8.4.3 Purchasing Information

Purchasing information may take many forms. Purchasing documents, however, is generally a Purchase Order or Purchase Order Requisition in additions to the terms and conditions stated on this clause.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

To control its provision of Products or Services, Auburn Manufacturing considers, as applicable, the following:

- Availability of information that describes characteristics of the product This information can include drawings parts lists, materials and process specifications
- Availability of the Work Instructions if necessary. Work Instructions can include process flow charts, production documents (e.g., manufacturing plans, travelers, routers, work orders, process cards) and inspection documents.
- Use of the suitable equipment. Suitable equipment can include product specific tools (e.g., jigs, fixtures, molds) software programs.
- Availability and use of the Monitoring and Measuring Devices
- Accountability for all product during manufacture (e.g., parts quantities, split orders, non-conforming product);
- the implementation of actions to prevent human error;
- Evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized;
- Provision for the prevention, detection, and removal of foreign objects;

- Monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality;

8.5.1.1 Control of Production Equipment, Tools and Software Programs

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes are validated prior to final release for production and are be maintained. Special storage requirements, if applicable, are defined for production equipment or tooling including any necessary periodic preservation or condition checks.

Exemptions

Equipment solely used for supporting the facilities, tooling is exempt from this procedure; this includes compressors, vehicles, air handling systems, lighting, etc.

8.5.1.2 Validation and Control of Special Processes

Now, Auburn Manufacturing does not utilize any in-house “special processes” where the result of the process cannot be verified by subsequent monitoring or measurement. Any such special processes are sent to outside suppliers, and controlled and an outsourced process.

8.5.1.3 Production Process Verification – First Article Inspection Report

First Article Inspections shall be performed at the discretion of Quality and/or when required by customer or contract requirements.

Such First Article Inspections are a complete inspection of a completed part, of all dimensions and criteria, to validate the production processes and equipment.
The product used shall be a representative item from the first production run a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements.
This process shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).
Auburn Manufacturing uses forms and/or computer software to satisfy first article requirements per AS9102; where the customer dictates a format for First Article reporting, these formats will be used instead.

8.5.2 Identification and Traceability

Where appropriate, Auburn Manufacturing identifies its products or other critical process outputs by suitable means. Such identification includes the status of the products with respect to monitoring and measurement requirements. Unless otherwise indicated as nonconforming, pending inspection or disposition, or some other similar identifier, all products shall be considered conforming and suitable for use.

Auburn Manufacturing maintains the identification of the configuration of the products and services to identify any differences between the actual configuration and the required configuration.

The documented procedure defines these methods in detail.

If unique traceability is required by contract, regulatory, or other established requirement, Auburn

Manufacturing controls and records the unique identification of the Auburn Manufacturing This shall include, as appropriate:

a) product identification to be maintained throughout the product life

b) the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap)

c) for an assembly, the ability to trace its components to the assembly and then to the next higher assembly

d) for a product, a sequential record of its production

- Where appropriate Auburn Manufacturing identifies product throughout product realization as follows:
- Maintains identification of the configuration of the product to identify differences between the actual configuration and the agreed configuration;
- Identifies product with respect to monitoring and measurement requirements throughout product realization;
- Establishes and documents controls for the media when acceptance authority media such as stamps, electronic signatures or passwords are used;
- Provides for (suitably to the level of traceability required by the contract, regulatory, or other established requirement):
    - Identification to be maintained throughout the product life
    - Traceability of all products manufactured from the same batch of raw material or from the same manufacturing batch, as well as the destination (delivery, scrap) of all products of the same batch
    - Identification of the assembly components
    - Sequential record of a given product manufacture, inspection, etc.

Auburn Manufacturing controls and records the unique identification of the product wherever traceability is a specified requirement and maintains records.

8.5.3 Property Belonging to Customers or External Providers

Auburn Manufacturing exercises care with customer or supplier property while it is under the organization's control or being used by the organization. Upon receipt, such property is identified, verified, protected and safeguarded. If any such property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer or supplier and records maintained.

For customer intellectual property, including customer furnished data used for design, production and / or inspection, this is identified by customer and maintained and preserved to prevent accidental loss, damage or inappropriate use.

NOTE: A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property, and personal data.

8.5.4 Preservation

Auburn Manufacturing preserves conformity of product during internal processing and delivery to the intended destination. This preservation includes cleaning, FOD control, special handling for sensitive products, marking and labeling including safety warnings, shelf life control and stock rotation, and special handling for hazardous materials. Preservation also applies to the constituent parts of a product.
The documented procedure defines the methods for preservation of product and the documented procedure defines the methods for preventing, identifying and controlling foreign objects.

NOTE: Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

Preservation of outputs shall also include, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:

8.5.5 Post Delivery Activities

Auburn Manufacturing will meet the requirements for post-delivery activities associated with the products and services. The customer requirements and feedback will always be part of the process. In determining the extent of post-delivery activities that are required, the organization shall consider, the statutory and regulatory requirements of the customer as applicable. In the event that there are potential undesired consequences associated with its products and services it will be dealt with the existing processes. Note: the lifetime and collection of data is not possible with the product due to the fact that once it is installed and removed it is scrapped. Customer is always responsible for updating any standard, prints and documentation and assistance – if requested, it will be provided.

When problems are detected after delivery, the organization shall take appropriate action including investigation and reporting.

8.5.6 Control of Changes

Auburn Manufacturing] reviews and controls both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with all requirements.

The organization shall retain documented information describing the results of the review of changes, the person (President, Production Manager or Quality Manager), authorizing the change, and any necessary actions arising from the review.

8.6 Release of Products and Services

Auburn Manufacturing monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process in accordance with planned arrangements; Evidence of conformity with the acceptance criteria shall be maintained. See Monitoring and Measurement of Product System Procedure.

Measurement requirements for product or service acceptance are documented. This documentation is part of the production documentation, and includes:

- Criteria for acceptance and/or rejection,

- Where in the sequence measurement and testing operations are performed?
- A record of the measurement results, (at a minimum, indication of acceptance or rejection) and
- Type of measurement instruments required, and any specific instructions associated with their use.

When critical items, including key characteristics have been identified, they are monitored and controlled.

When the organization uses sampling inspection as a means of product acceptance, the plan is statistically valid and appropriate for use.

Where product is released for production use pending completion of all required measurement and monitoring activities, it will be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Where required to demonstrate product qualifications, the organization will ensure that records provide evidence that the product meets the defined requirements.

The release of product and delivery of service to the customer will not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority (Typically the President or Quality Manager) and where applicably by the customer

The organization shall retain documented information on the release of products and services. The documented information shall include:

a. evidence of conformity with the acceptance criteria;
b. traceability to the person(s) authorizing the release.

8.7 Control of Non-Conforming Product

Auburn Manufacturing ensures that product which does not conform to the requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with non-conforming product are defined in the Control of Non-Conforming Product System Procedure

The term “non-conforming product” includes non-conforming product returned from a customer.

Responsibility for review and authority for the disposition of the non-conforming product, and the process for approving personnel making these decisions is defined in the Control of Non-Conforming Product System Procedure and includes:

- Taking action to eliminate the detected non-conformity;
- The Quality Manager or President authorizes its use, release or acceptance under concession by the relevant authority and where applicable by the customer;
- Taking action to preclude its original intended use or application.
- By taking action appropriate to the effects, or potential effects of the nonconformity when nonconforming product is detected after delivery or use has started

- Provides for timely reporting of delivered non-conforming product

Taking action necessary to contain the effect of the non-conformity on other processes or products

Dispositions of use-as-is or repair, will only be used after approval by an authorized representative of the organization responsible for design:

The company will not use dispositions of use as is or repair unless specifically authorized by the customer, if the non-conformity results in a departure from the contract requirements

Product dispositioned for scrap is conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

Records of the nature of non-conformities and any subsequent actions taken, including concessions obtained are maintained.

When non-conforming product is corrected, it is subjected to re-verification to demonstrate conformity to the requirements.

When non-conforming product is detected after delivery or use has started, Auburn Manufacturing takes action appropriate to the effects or potential effects of the non-conformity.

In addition to any contract or regulatory authority reporting requirements, Auburn Manufacturing system provides for timely reporting of delivered non-conforming product that may affect reliability or safety. Notification includes a clear description of the non-conformity, which includes as necessary, parts affected, customer and/or organization part numbers, quantity, and date delivered.

Note: Parties requiring notification of the non-conforming product may include customers, distributors, regulatory authorities, suppliers and internal organizations.

8.7.2 The organization shall retain documented information that:

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

9.0 Monitoring, Measurement, Analysis, and Evaluation

9.1.1 General

Auburn Manufacturing has determined which aspects of its quality management system must be monitored and measured, as well as the methods to utilize and records to maintain, within this Business Management System and subordinate documentation.

Monitoring and measurement of the processes, as defined in 4.4 above, ensure that Management evaluates the performance and effectiveness of the quality management system itself.

a. what needs to be monitored and measured;

b. the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results;

c. when the monitoring and measuring shall be performed;

d. when the results from monitoring and measurement shall be analyzed and evaluated.

The organization shall evaluate the performance and the effectiveness of the quality management system.

The organization shall retain appropriate documented information as evidence of the results.

9.1.2 Customer Satisfaction

As one of the measurements of the performance of the management system, Auburn Manufacturing monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information include: On-Time Delivery, Quality to Customer, and Customers feedback.

NOTE: Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims, and dealer reports.

Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. The organization shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

9.1.3 Analysis of Data

Auburn Manufacturing determines, collects and analyzes appropriate data to demonstrate suitability and effectiveness of the QMS and to evaluate where continual improvement of the QMS can be made. Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.

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

Statistical techniques used may be defined in appropriate documented procedures; in all cases, the methods are based on established standards or are otherwise determined to be statistically valid.

9. 2 Internal Audit

Auburn Manufacturing has a documented procedure established to define the process for conducting internal audits at planned intervals to determine whether the QMS:

- Conforms to the requirements of the international standards and to the QMS requirements established by the organization;
- Is effectively implemented and maintained;
- Include customer contractual requirements

The Audit program has been planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods will be defined. The selection of auditors and conduct of audits will ensure objectivity and impartiality of the audit process. Auditors will not audit their own work.

Management responsible for the area being audited must ensure that *any necessary corrections and corrective* actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities include verification of the actions taken and reporting of the verification results per the Corrective Actions System

Records of the audits and their results shall be maintained

Internal audits also meet contract and/or regulatory requirements.

9.3 Management Review

9.3.1

The President of Auburn Manufacturing reviews the management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The review includes assessing opportunities for improvement, and the need for changes to the management system, including the ***Quality Policy*** and quality objectives.

Management review frequency, agenda (inputs), outputs, required members, actions taken and other review requirements are defined in the documented procedure.

Records from management reviews are maintained.

9.3.2 Review Input

Assessment of the QMS is based on a review of the information inputs to the management reviews. These inputs include the following:

1. customer satisfaction and feedback from relevant interested parties;
2. the extent to which quality objectives have been met;
3. process performance and conformity of products and services;
4. nonconformities and corrective actions;
5. monitoring and measurement results;
6. audit results;
7. the performance of external providers;
8. on-time delivery performance;

d. the adequacy of resources;

e. the effectiveness of actions taken to address risks and opportunities (see 6.1);

f. opportunities for improvement.

9.3.3 Review Output

During review meetings, the Management Representative will identify appropriate actions to be taken regarding the following issues:

- Improvement of the effectiveness of the QMS and its processes;
- Improvement of product versus customer requirements;
- Resource needs.
- risks identified.

Responsibility for required actions is assigned to the Top Management Team. Any decisions made during the review meeting, assigned actions, and their due dates are recorded in the minutes of the management review.

10 Improvement

10.1 General

Auburn Manufacturing continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. Management monitors the implementation of improvement activities and evaluates the effectiveness of results.

Note: NOTE: Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation, and re-organization.

The results of analysis shall be used to evaluate:

g) conformity of products and services;

h) the degree of customer satisfaction;

i) the performance and effectiveness of the management system;

j) the effectiveness of planning;

k) the effectiveness of actions taken to address risks and opportunities;

l) the performance of external providers;

m) other improvements to the management system.

10.2 Corrective Action

10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall:

a. react to the nonconformity and, as applicable:

1. take action to control and correct it;

2. deal with the consequences;

Auburn Manufacturing takes action to eliminate causes of non-conformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the non-conformities encountered.

The Corrective Actions System Procedure defines requirements for:

- Reviewing non-conformities (including customer complaints);
- Determining causes of non-conformities;
- Evaluating the need for action to ensure that non-conformities do not recur;
- Determining and implementing action needed;
- Record of the results of action taken;
- Review the effectiveness of the corrective action taken;
- Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause;
- Specific actions where timely or effective corrective actions are not achieved.
- Determining if additional non-conforming product exists based on the cause of the non-conformity and taking further action when required

10.2.2 The organization shall retain documented information as evidence of:

a. the nature of the nonconformities and any subsequent actions taken;
b. the results of any corrective action.

10.3 Continual Improvement

Auburn Manufacturing continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. Management monitors the implementation of improvement activities and evaluates the effectiveness of results.

Note: Continual Improvement opportunities can result from lessons learned, problem resolution and the benchmarking of best practices.