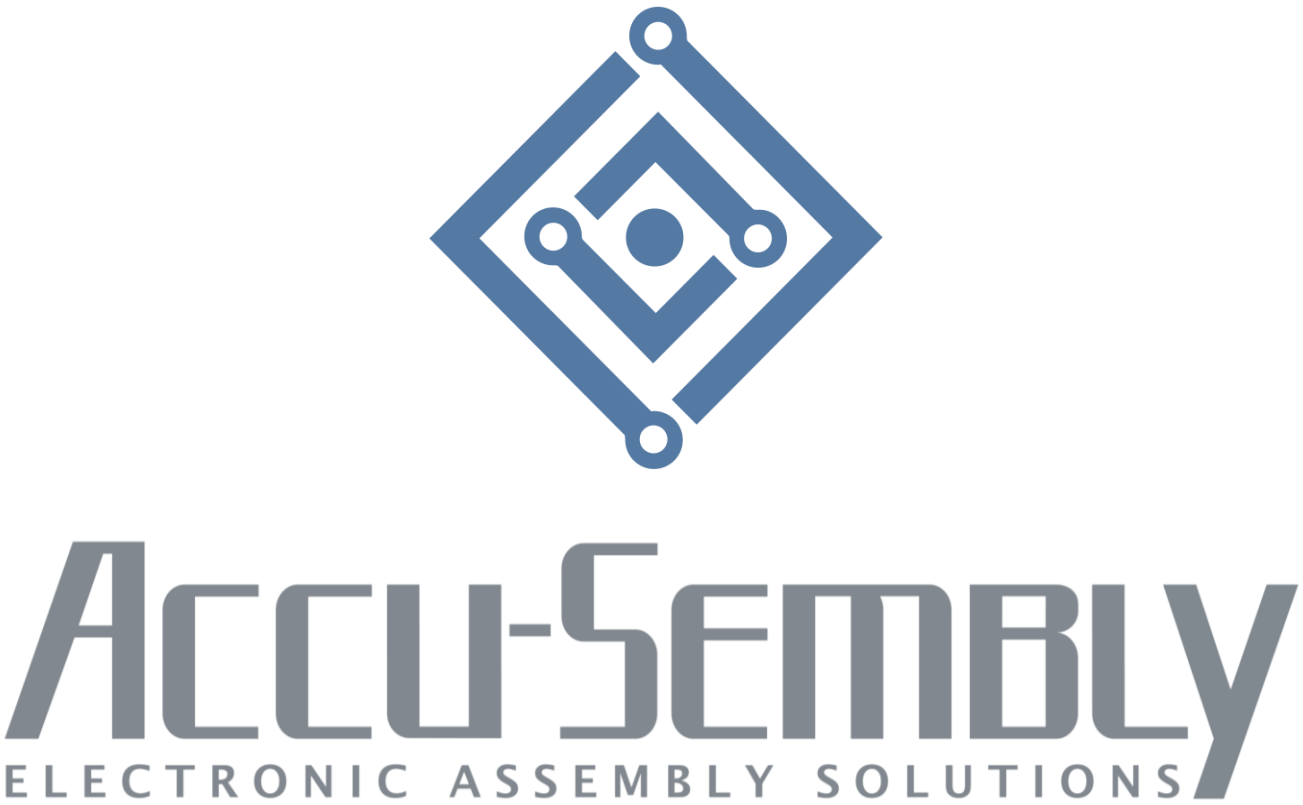

QUALITY MANUAL

Revision 5.2

Issued June 24, 2020

Conforms to AS9100 Rev. D and ISO 9001:2015

TABLE OF CONTENTS

0.0 Revision History and Approval

Revision history, effective date and change summaries for this quality manual are located on the company server in the ***Document Master List*** and associated files.

0.1 Authorization

This Quality Manual is published under the authority of the President/CEO of Accu-sembly, Inc. It is intended to establish and communicate the Quality Policy and the structure of the Quality Management System for Accu-sembly. This Quality Manual will be updated as necessary to reflect changes in policies and quality management practices.

0.2 Distribution Policy

This manual is controlled, maintained and issued by the Quality Manager (appointed as the Quality Management Representative) and is reviewed and approved by the appropriate staff and Top Management of Accu-sembly. It is available to all Accu-sembly customers, suppliers, and company personnel.

It can be viewed online at http://www.accu-sembly.com. Printed copies of this document are for reference only and are uncontrolled. Before using an uncontrolled document, it is the holder's responsibility to verify that the revision is current.

0.3 Abbreviations

The following abbreviations may be used throughout this and related documents:

QM: Quality Manual

QMR: Quality Management Representative

QMS: Quality Management System

1.0 Welcome to Accu-sembly, Inc.

Accu-sembly is an experienced, customer-focused contract manufacturer of electronic assemblies for a variety of industries and customers. Established in 1983, Accu-sembly, Inc. is located in Duarte, California, and employees approximately 100 staff. There are 25,000 square feet of manufacturing space and 5,000 square feet of office space. The company is a family run business and is currently headed by President/CEO John Hykes. Accu-sembly prides itself in having a personal touch with its clientele through every step of the assembly process.

Accu-sembly's materials services include full turnkey procurement and consigned inventory management. Our production facilities include fully-automated, multi-machine pick and place SMT lines, dedicated lead and lead-free wave-solder lines, automated optical inspection machines and x-ray validation.

Accu-sembly originally achieved registration to the international quality management standard ISO 9001 in 1998. The company is currently registered to ISO 9001:2015 and AS9100 Rev D.

2.0 About The Accu-sembly 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.

This manual presents "Notes" which are used to define how Accu-sembly 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. *Notes appear in italics, with gray background.*

Where subordinate or supporting documentation is reference in this manual, these are indicated by ***bold italics***.

3.0 Terms and Definitions

Accu-sembly 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

Accu-sembly – Accu-sembly, Inc.

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.)

Nonconforming Product Terminology

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 not specified in the original design, or through altering pre-existing design features.

Scrap: The discard of nonconforming product in lieu of rework or repair.

Other AS9100 Terminology

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. (Examples can include, but are not limited to, the false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics.)

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

Key Characteristics: 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.

Procedure: Specified way to carry out an activity or a process.

Process: Set of interrelated or interacting activities, which transforms inputs into outputs.

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.

Special Process: A process where conformity of the resulting product cannot be readily or economically verified.

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.

Suspect Unapproved Part: A product that might not have been or is suspected of not having been produced in accordance with applicable laws and regulations.

System: Set of interrelated or interacting elements.

Traceability: Ability to trace the history, application or location of that which is under consideration.

Validation: Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. *NOTE: The term "validated" is used to designate the corresponding status.*

Verification: Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. *NOTE: The term "verified" is used to designate the corresponding status.*

Work Transfer: The transfer of work which can include transfer from one organization facility to another, from Accu-sembly to the supplier or from one supplier to another supplier.

4.0 Context of the Organization

4.1 Understanding the Organization and Its Context

Accu-sembly is committed to defining our position in the marketplace and understanding how relevant factors arising from legal, political, economic, social and technological issues influence our strategic direction and our organizational context. Accu-sembly identifies, analyzes, monitors and reviews factors that may affect our ability to satisfy our customers and stakeholders, as well as factors that may adversely affect the stability of our process or our management system's integrity.

To ensure that our QMS is aligned with our strategy, whilst taking account of relevant internal and external factors, we initially analyze pertinent information in order to determine potential impact on our context and subsequent business strategy. Accu-sembly then monitors and reviews this information to ensure that a continual understanding of each group's requirements is derived and maintained. To facilitate the understanding or our context, we regularly consider issues that influence our context during management review meetings and are conveyed via minutes and business planning documents.

The output from this activity is evident as an input to the consideration of risks and opportunities, and the actions that we take to address them. Refer to Section 6.1 for more information about our risk and opportunity management framework.

INTERNAL ISSUES	EXTERNAL ISSUES
Owners	Customers & Suppliers
Employees	Markets & Competition
Performance	Regulatory & Statutory
Capacity	Economic backdrop
Values & Culture	Cultural & Social
Innovation & Knowledge	Technological

INTERESTED PARTIES	NEEDS & EXPECTATIONS
Customers	Price, Reliability & Value
Owners	Profitability & Growth
Employees	Shared Values & Security
Suppliers	Beneficial Relationships
Regulatory & Statutory	Compliance & Reporting

4.2 Understanding the Needs and Expectations of Interested Parties

Accu-sembly recognizes that we have a unique set of interested parties whose needs and expectations change and develop over time, and furthermore, that only a limited set of their respective needs and expectations are applicable to

our operations or to our quality management system. Such needs and expectations broadly include those shown in the table in 4.1 above.

To ensure that our products and processes continue to meet all relevant requirements, we identify and assess the potential impact of any relevant needs and expectations that may be elicited from the interested parties.

Where appropriate, to ensure that our processes are aligned to deliver the requirements of our interested parties, we convert relevant needs and expectations into requirements which become inputs to our QMS and to our product and service designs.

4.3 Determining the Scope of the Quality Management System

Based on an analysis of the above issues of concern, interests of stakeholders, and in consideration of its products and services, Accu-sembly has determined the scope of the management system as follows:

> Accu-sembly located in Duarte, California, provides manufacturing services of electronic assemblies for commercial, industrial and aerospace industries within the United States.

The quality system applies to all processes, activities and employees within the company. The facility is located at:

1835 Huntington Drive
Duarte CA 91010
Phone: 626-357-3447
Fax: 626-357-0778
Web: www.accu-sembly.com

The following table identifies AS9100 and ISO 9001 standards requirements not applicable to our organization and provides a brief narrative justifying their exclusion from the scope of our QMS:

Clause/ Sub-clause	Exclusion	Justification
8.3	Design and Development of Products and Services	Accu-sembly is a print-based, contract manufacturer and does not perform design and development. Accu-sembly has no responsibility to define the product fit, form, or function. Designs are specified by our customers via their drawings and specifications.

4.4 Quality Management System and Its Processes

4.4.1 Process Identification

Accu-sembly has adopted a process approach for its management system. By identifying the top-level processes within the company, and then managing each of these discretely, this reduces the potential for nonconforming products and services discovered during final processes or after delivery. Instead, nonconformities and risks are identified in real time, by actions taken within each of the top-level processes.

Note: not all activities are considered “processes” – the term “process” in this context indicates the activity has been elevated to a higher level of control and management oversight. The controls indicated herein are applicable only to the top-level processes identified.

The following top-level processes have been identified for Accu-sembly:

- Quoting & Contract Review
- Quality Planning
- Purchasing & Inventory
- Production & Delivery
- QMS Management

Each process may be supported by other activities, such as tasks or sub-processes. Monitoring and control of top level processes ensures effective implementation and control of all subordinate tasks or sub-processes.

Each top-level process has a ***Process Definition*** document which defines:

- applicable inputs and outputs
- process owner(s)
- applicable responsibilities and authorities
- applicable risks and opportunities
- critical and supporting resources
- criteria and methods employed to ensure the effectiveness of the process
- quality objectives related to that process

The sequence of interaction of these processes is illustrated in Appendix A.

Note: Appendix A represents the typical sequence of processes, and may be altered depending on customer or regulatory requirements at the job or contract level, as needed.

4.4.2 Process Controls & Objectives

Each process has at least one objective established for it; this is a statement of the intent of the process. Each objective is then supported by at least one "metric" or key performance indicator (KPI) which is then measured to determine the process' ability to meet the quality objective.

Note: some processes have multiple objectives and multiple metrics. This is determined by the nature of the process, it's impact on products and services, and associated risks.

Note: Whereas ISO 9001 discusses process measurements and "quality objectives" as separate concepts, Accu-sembly combines them; i.e., quality objectives are used to control the processes. Additional objectives for products and services may be assigned, but these will also be used to measure process effectiveness.

Throughout the year, metrics data is measured and gathered by process owners or other assigned managers, in order to present the data to Top Management. The data is then analyzed by Top Management in order that Top Management may set goals and make adjustments for the purposes of long-term continual improvement.

The specific quality objectives for each process are defined in the applicable ***Process Definition***.

Metrics, along with current standings and goals for each objective, are recorded in records of management review.

When a process does not meet a goal, or an unexpected problem is encountered with a process, the corrective and preventive action process may be implemented to research and resolve the issue. In addition, opportunities for improvement are sought and implemented, for the identified processes.

4.4.3 Outsourced Processes

Any process performed by a third party is considered an "outsourced process" and must be controlled, as well. The company's outsourced processes, and the control methods implemented for each, are defined in ***Outsourced Processes***.

The type and extent of control to be applied to the outsourced process take into consideration:

a) the potential impact of the outsourced process on the company's capability to provide product that conforms to requirements,

b) the degree to which the control for the process is shared, and

c) the capability of achieving the necessary control through the purchasing contract requirements.

5.0 Leadership

5.1 Leadership & Commitment

5.1.1 General

Top Management of Accu-sembly 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;

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.

Note: "business processes" such as accounting, employee benefits management and legal activities are out of scope of the QMS.

5.1.2 Customer focus

Top Management of Accu-sembly 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; and

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

Top Management 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 Quality Policy of Accu-sembly is as follows:

Accu-sembly strives for "Total satisfaction through quality performance."

By commitment to: Compliance with applicable requirements

Continuous review and improvement of the quality system

Communication of quality objectives throughout the organization

5.3 Organizational Roles Responsibilities and Authorities

Top Management has assigned responsibilities and authorities for all relevant roles in the company. These are communicated through the combination of the ***Organizational Chart*** and Job Descriptions.

The QA Manager has been assigned the role of QMS Management Representative (QMR) when having a single point of contact to represent the Accu-sembly quality system is useful or required by customer or regulations. Other duties of the QMR may be defined herein or within other documented procedures.

In addition, the following overall QMS responsibilities and authorities are assigned as follows:

Responsibility	Assigned To
• Ensuring that the management system conforms to applicable standards	• Top Management
• Ensuring that the processes are delivering their intended outputs	• Applicable process owners
• Reporting on the performance of the management system and providing opportunities for improvement for the management system	• Quality Assurance Manager and/or QMR
• Ensuring the promotion of customer focus throughout the organization	• Top Management
• Ensuring that the integrity of the management system is maintained when changes are planned and implemented	• Top Management

6.0 Planning

6.1 Actions to Address Risks and Opportunities

The overall aim of risk and opportunity management within Accu-sembly is to ensure that organizational capabilities and resources are employed in an efficient and effective manner to take advantage of opportunities and to mitigate risks.

Top management are responsible for incorporating risk based thinking in to our organization's culture. This includes the establishment of risk management policies and targets to ensure effective implementation of risk and opportunity management principles and activities by:

- Providing sufficient resources to carry out risk and opportunity management activities;
- Assigning responsibilities and authorities for risk and opportunity management activities; and
- Reviewing information and results from audits and risk and opportunity management activities.

The scope of Accu-sembly's risk and opportunity management process includes the assessment of the internal and external issues identified in Section 4.1, and the assessment of the needs and expectations of any interested parties identified in Section 4.2. Risk and opportunity management is undertaken as part of Accu-sembly's day to day operations and is captured at the strategic level, department level, process level and order level.

Establishing such a hierarchy for capturing risk and opportunity ensures that each is managed at the most appropriate level within our organization. Typically, the following categories are assigned to each level in the hierarchy as shown in the table below.

BUSINESS HIERARCHY	RISK / OPPORTUNITY
Strategic level	Budgets & profitability
Department level	Performance & efficiency
	Resources & targets
Process level	Evaluation & assurance
Order level	Requirements & expectations

Accu-sembly has classified its risk appetite as the amount of risk that we are willing to accept in pursuit of an opportunity or the avoidance of risk where each pertains to product and/or system conformity, and which reflect the following considerations:

- Risk management philosophy per order or process;
- Capacity to take on or mitigate risk;
- Our objectives, business plans and respective stakeholder demands;
- Evolving industry and market conditions;
- Tolerance for failures.

Accu-sembly uses registers to help record, assess, respond, review, report, monitor and plan for the risks and opportunities that we perceive to be relevant. The registers allow our organization to methodically assess each risk and to study each opportunity associated with our organizational context and the needs and expectations of our interested parties. The register records the controls and treatments of risks and opportunities and preserves this knowledge as documented information. See ***Risk and Opportunity Management***

6.2 Quality Objectives and Planning to Achieve Them

As part of the adoption of the process approach, Accu-sembly utilizes its process objectives, as discussed in 4.4 above, as the main quality objectives for the QMS. These include overall product-related quality objectives; additional product-related quality objectives may be defined in work instructions or customer requirements.

The process objectives have been developed in consideration that they:

- be consistent with the quality policy;
- be measurable;
- take into account applicable requirements;
- be relevant to conformity of products and services and to enhancement of customer satisfaction;
- be monitored;
- be communicated;
- be updated as appropriate.

Process quality objectives are defined in the minutes of management review per section 9.3 below.

The planning of process quality objectives is defined in section 4.4. above.

6.3 Planning of Changes

Changes to the quality management system and its processes are carried out in a planned manner per the procedure ***Change Management.***

7.0 Support

7.1 Resources

7.1.1 General

Accu-sembly determines and provides the resources needed:

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

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

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

7.1.3 Infrastructure

Accu-sembly determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

a) buildings, workspace and associated facilities;

b) process equipment, hardware and software;

c) supporting services such as transport;

d) information and communication technology.

Equipment is validated per the procedure ***Validation of Equipment*** and maintained per the procedure ***Preventive Maintenance.***

7.1.4 Environment for the Operation of Processes

Accu-sembly provides a clean, safe and well-lit working environment. The Top Management of Accu-sembly 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 job documentation. Where special work environments have been implemented, these shall also be maintained per 7.1.3 above.

Human factors are considered to the extent that they directly impact on the quality of products and services.

Note: Social, psychological and safety aspects of the work environment are managed through activities outside of the scope of the management system. Only work environment aspects which can directly affect process efficiency or product and service quality are managed through the management system.

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

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

Accu-sembly ensures these resources are suitable to the type of monitoring and measurement activities being undertaken and are maintained to ensure their continuing fitness for their purpose.

7.1.5.2 Measurement Traceability

Where equipment is used for critical measurement activities, such as inspection and testing, these shall be subject to control and either calibration or verification; see the procedure ***Calibration of Equipment.***

Note: Calibration and measurement traceability is not employed for all measurement devices. Instead, Accu-sembly determines which devices will be subject to calibration based on its processes, products and services, or in order to comply with specifications or requirements. These decisions are also based on the importance of a measurement, and considerations of risk.

7.1.6 Organizational Knowledge

Accu-sembly 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, Accu-sembly 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 on the basis of appropriate education, training, skills and experience. The documented procedure ***Hiring and Training*** defines these activities in detail.

Note: the management system does not include other aspects of Human Resources management, such as payroll, benefits, insurance, labor relations or disciplinary actions.

7.3 Awareness

Training and subsequent communication ensure that staff are aware of:

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.

7.4 Communication

Top Management of Accu-sembly ensures internal communication takes place regarding the effectiveness of the management system. Internal communication methods include:

a) use of corrective and preventive action processes to report nonconformities or suggestions for improvement

b) use of the results of analysis of data

c) meetings (periodic, scheduled and/or unscheduled) to discuss aspects of the QMS

d) use of the results of the internal audit process

e) internal emails

f) company newsletters and bulletin boards

Accu-sembly's "open door" policy which allows any employee access to Top Management for discussions on improving the quality system

7.5 Documented Information

The management system documentation includes both documents and records.

Note: the ISO 9001:2015 standard uses the term "documented information"; Accu-sembly does not use this term, but instead relies on the terms "document" and "record" to avoid confusion. In this context the terms are defined by Accu-sembly as provided for in section 3.0 above. Documents and records undergo different controls as defined herein.

Documents required for the management system are controlled in accordance with procedure ***Control of Documents.*** 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 ***Control of Records*** 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.

Configuration documents are subject to additional controls per section 8.1.2 below.

These controls are applicable to those records which provide evidence of conformance to requirements; this may be evidence of product and service requirements, contractual requirements, procedural requirements, or statutory/regulatory compliance. In addition, quality records include any records which provide evidence of the effective operation of the management system.

8.0 Operation

8.1 Operational Planning and Control

Accu-sembly plans and develops the processes needed for realization of its products and services. Planning of product and 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 (see section 4.0 above), current resources and capabilities, as well as product and service requirements.

Such planning is accomplished through:

a) determining the requirements for the products and services;

b) establishing criteria for the processes and the acceptance of products and services;

c) determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services;

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

e) determining, maintaining and retaining 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 and services to their requirements;

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

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

h) determining the process and resources to support the use and maintenance of the products and services;

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

j) establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

Due to the nature of Accu-sembly's work, formal project management is not implemented. Instead, each customer purchase order is treated as a unique project and planned for accordingly. The output of this planning is the Sales Order Binder, which contains a unique Quality Plan, Traveler, related drawings and assembly instructions, inspection packages, process worksheets, and, as applicable, quality and/or process alerts, operator checklists, and specifications that show dimensions, characteristics, tolerances, and any key characteristics identified by Accu-sembly or the customer. Likewise, these instructions define any processes, documents or resource requirements specific to fulfilling the customer purchase order. Inspection, testing and other monitoring steps are defined in the Quality Plan.

Process controls include methods to control the temporary or permanent transfer of work, to ensure the continuing conformity of the products and services. This will consider how work transfer impacts and risks are managed.

For transfers between internal processes, or within Accu-sembly divisions, these are controlled through normal work planning methods.

Changes to operational processes are done in accordance with the document ***Change Management***.

Outsourced processes and the means by which Accu-sembly controls them are defined in the documented procedure ***Outsourced Processes.*** More complex work transfers are documented on the ***Outsource Worksheet*** form. For transfers between Accu-sembly and an external service provider, or between external providers, these are controlled under the Purchasing requirements defined in section 8.4 below.

8.1.1 Operational Risk Management

Operational risk management is conducted to manage the risks related to product and service realization requirements; see section 6.1 on risk and opportunity management above.

8.1.2 Configuration Management

Accu-sembly plans, implements, and controls configuration management activities as appropriate to its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This is defined in the documented procedure ***Configuration Management.*** This includes document control for configuration documents, and change control for configured items.

8.1.3 Product Safety

Operational controls shall be implemented to assure product safety during the entire product life cycle, where this is appropriate relative to Accu-sembly's products and services. These activities may include:

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

Operational controls shall be implemented to assure the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer. These activities are defined in greater detail in the documented procedure ***Counterfeit Part Control***.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Accu-sembly has implemented effective communication with customers in relation to:

a) providing information relating to products and services;

b) handling enquiries, contracts or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property;

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

8.2.2 Determining the Requirements Related to Products and Services

During the intake of new business Accu-sembly captures:

a) the requirements for the products and services, including any applicable statutory and regulatory requirements and other requirements deemed necessary by Accu-sembly

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

c) special requirements (see 8.5.1 below)

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

These activities are defined in greater detail in the procedure ***Quoting and Contract Review.***

8.2.3 Review of Requirements Related to Products and Services

Once requirements are captured, Accu-sembly reviews the requirements prior to its commitment to supply the product and 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 has the ability to 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 ***Quoting and Contract Review.***

8.2.4 Changes to Requirements for Products and Services

Accu-sembly updates all relevant requirements and documents when the requirements are changed, and ensure that all appropriate staff are notified; see the documented procedure ***Change Management.***

8.3 Design and Development of Products and Services

Accu-sembly claims exclusion to Design and Development of Products and Services.

8.4 Control of Externally Provided Processes, Products and Services

Accu-sembly ensures that purchased product and service conform to specified purchase requirements.

Accu-sembly evaluates and selects suppliers based on their ability to supply products and services in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation are established.

Purchases are made via the release of formal purchase orders and/or contracts which clearly describe what is being purchased. Received products or services are then verified against requirements to ensure satisfaction of requirements. Suppliers who do not provide conforming products or services may be requested to conduct formal corrective action.

These activities are further defined in the documents ***Purchasing*** and ***Receiving***.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

To control its provision of products and services, Accu-sembly considers, as applicable, the following:

a) the availability of documents or records that define the characteristics of the products and services as well as the results to be achieved;

b) the availability and use of suitable monitoring and measuring resources;

c) the implementation of monitoring and measurement activities;

d) the use of suitable infrastructure and environment;

e) the appointment of competent persons, including any required qualifications;

f) the validation and revalidation of special processes if applicable (see below);

g) the implementation of actions to prevent human error;

h) the implementation of release, delivery and post-delivery activities;

i) the establishment of criteria for workmanship;

j) the accountability for all products during production;

k) the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;

l) the determination of methods to measure variable data;

m) the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;

n) the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;

o) the provision for the prevention, detection, and removal of foreign objects;

p) the control and monitoring of utilities and supplies to the extent they affect conformity to product requirements;

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

Where special requirements, key characteristics and/or critical items are identified or deemed appropriate, the processes will be planned and controlled to manage these aspects. See the procedure ***Special Requirements, Critical Items & Key Characteristics*** for guidance on this subject.

Where appropriate, special statistical techniques may be used to control or monitor operational processes. In such cases, the techniques selected shall be based on known standards or otherwise justified as statistically valid. This includes sampling plans when sampling is used for inspection, testing or other purposes.

8.5.1.1 Control of Equipment, Tools and Software Programs

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes are validated prior to final release for production and are maintained. Special storage requirements, if applicable, are defined for production equipment or tooling including any necessary periodic preservation or condition checks. This is further defined in the ***Validation of Equipment*** procedure.

8.5.1.2 Validation and Control of Special Processes

Accu-sembly utilizes some "special processes" where the result of the process cannot be verified by subsequent monitoring or measurement. The special processes in use and the methods of validation of each are defined in the document ***Special Processes.*** Special processes sent to outside suppliers are controlled as an outsourced process per ***Outsourced Processes.***

8.5.1.3 Production Process Verification

Production processes in use as of October 2017 are approved based on previous experience.

New Production processes are validated prior to use or implementation. This may include running test product through the new process or equipment, or by performing a First Article Inspection on a part produced by the process, tooling or equipment. First Article is discussed further in section 8.6.4 below.

8.5.2 Identification and Traceability

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

Accu-sembly maintains the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration; see the documented procedure ***Configuration Management.***

If unique traceability is required by contract, regulatory, or other established requirement, Accu-sembly controls and records the unique identification of the product and service. 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

The documented procedure ***Identification and Traceability*** defines these methods in detail.

8.5.3 Property Belonging to Customers or External Providers

Accu-sembly 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.

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

This activity is defined in greater detail in the document ***Control of Third-Party Property.***

8.5.4 Preservation

Accu-sembly 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 ***Preservation of Product*** defines the methods for preservation of product and the documented procedure ***FOD Control*** defines the methods for preventing, identifying and controlling foreign objects.

8.5.5 Post-Delivery Activities

As applicable, Accu-sembly conducts the following activities which are considered “post-delivery activities”:

- Rework of product under warranty

Post-delivery activities are conducted in compliance with the management system defined herein. In determining the extent of post-delivery activities that are required, Accu-sembly considers:

a) statutory and regulatory requirements;

b) the potential undesired consequences associated with its products and services;

c) the nature, use and intended lifetime of its products and services;

d) customer requirements;

e) customer feedback;

f) collection and analysis of in-service data (e.g., performance, reliability, lessons learned);

g) control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul;

h) controls required for work undertaken external to the organization (e.g., off-site work);

i) product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).

When problems are detected after delivery, Accu-sembly takes appropriate action including investigation and reporting; see section 10.2.

8.5.6 Control of Changes

Accu-sembly reviews and controls both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with all requirements.

Process change management is defined in the document ***Change Management.***

Documents are changed in accordance with procedure ***Control of Documents***.

8.6 Release of Products and Services

Products and services undergo inspection and/or testing to ensure they meet all requirements at critical stages throughout the various processes, and then prior to final delivery.

Measurement requirements are documented; this documentation is part of the sales order documentation, and includes:

a) criteria for acceptance and / or rejection,

b) where in the sequence measurement and testing operations are performed, and

c) a record of the measurement results.

Test records will show actual test results data when required by specification or acceptance test plan.

Where required to demonstrate product and service qualification Accu-sembly will ensure that records provide evidence that the product and service meets the defined requirements.

When key characteristics have been identified, they are monitored and controlled as required.

Product is not used until it has been inspected or otherwise verified as conforming to specified requirements, except when released under positive-recall procedures pending completion of all required measurement and monitoring activities.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing release of products and services.

8.6.1 Receiving Inspection and Testing

Incoming raw materials, processed products or other critical received goods undergo inspection and/or testing at receiving, prior to entry into the production processes. These activities are defined in the documented procedure ***Receiving.***

8.6.2 In-Process Inspection and Testing

At defined stages throughout production, inspections and/or tests are conducted to ensure the products satisfy the requirements for that particular process or activity, prior to being released to the next process or activity. This is defined in ***Process Definition – Quality Planning*** and/or quality documentation specific to each sales order.

8.6.3 First Article Inspection

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).

Accu-sembly 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.

8.6.4 Final Inspection and Testing

Final acceptance criteria for products and services are defined in appropriate subordinate documentation. Reviews, inspections and tests are conducted at appropriate stages to verify that the product and service requirements have been met. This is done before products and services are released or services are delivered.

Each process utilizes different methods for measuring and releasing products and services. These methods are defined in ***Process Definition – Quality Planning***.

8.7 Control of Nonconforming Outputs

Accu-sembly ensures that products and services or other process outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The controls for such nonconformances are defined in ***Control of Nonconforming Product***.

9.0 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

Accu-sembly 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 Quality Manual and subordinate documentation.

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

9.1.2 Customer Satisfaction

As one of the measurements of the performance of the management system, Accu-sembly monitors information relating to customer perception as to whether the organization has met customer requirements.

The methods for obtaining and using this information include:

- recording customer complaints
- product rejections or returns
- repeat orders for product
- changing volume of orders for product
- trends in on-time delivery
- obtain customer scorecards from certain customers
- submittal of customer satisfaction surveys

The corrective and preventive action system shall be used to 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 and Evaluation

Accu-sembly analyzes and evaluates the data and information arising from monitoring and measurement in order to evaluate:

a) conformity of products and services;

b) the degree of customer satisfaction;

c) the performance and effectiveness of the quality management system;

d) if planning has been implemented effectively;

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

f) the performance of external providers;

g) the need for improvements to the quality management system.

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

Accu-sembly conducts internal audits at planned intervals to determine whether the management system conforms to contractual and regulatory requirements, to the requirements of ISO 9001 and AS9100, and to management system requirements. Audits also seek to ensure that the management system has been effectively implemented and is maintained.

These activities are defined in the document ***Internal Audits.***

9.3 Management Review

The Top Management 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 ***Management Review.***

Records from management reviews are maintained.

10.0 Improvement

10.1 General

Accu-sembly uses the management system to improve its processes, products and services. Such improvements aim to address the needs and expectations of customers as well as other interested parties, to the extent possible.

Improvement shall be driven by an analysis of data related to:

The results of analysis shall be used to evaluate:

a) conformity of products and services;

b) the degree of customer satisfaction;

c) the performance and effectiveness of the management system;

d) the effectiveness of planning;

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

f) the performance of external providers;

g) other improvements to the management system.

10.2 Nonconformity and Corrective Action

Accu-sembly takes corrective action to eliminate the cause of nonconformity in order to prevent recurrence. Likewise, the company takes preventive action to eliminate the causes of potential nonconformities in order to prevent their occurrence.

These activities are done through the use of the formal Corrective Preventive Action (***CPAR***) system, and are defined in the document ***Corrective and Preventive Action.***

10.3 Continual Improvement

Through the process effectiveness reviews, done as part of Management Review, Accu-sembly works to continually improve the suitability, adequacy and effectiveness of the quality management system. This includes seeking opportunities for improvement.

Appendix A: Overall Process Sequence & Interaction