THE CONTENTS OF THIS DOCUMENT ARE STRICTLY CONFIDENTIAL.

Its use is restricted to ACCESS ASSEMBLY employees who have signed a non-disclosure agreement.

Document Type: SOP Department: Quality	Approved By: John Babii	Implementation Date: 8/20/18

ACCESS ASSEMBLY LLC
custom assembly solutions

QUALITY MANUAL

Table of Contents

0.0 REVISION HISTORY

Rev.	Sec/Para Changed	Change Made	Author Name	Approval Date	CO
A	New	Initial Release	Jon Babii and Debbie Klein, Maestro Consulting	08/14/07	0001
B	Entire Document	Edited to ensure ISO requirements are met	Jon Babii	12/12/2007	0005
C	4.1, 5.4.1	Removed “customer” box from the Quality Chart, removed the time limit for the objectives, page 13	Jon Babii	12/19/2007	0006
D	Entire Document	Revise and update to ISO 9001:2008 standard	Jon Babii	12/07/2009	0009
E	Entire Document	Revise and update to ISO 9001:2015 standard	Jon Babii	2/28/18	
F	Entire Document	Revised and Updated per recommendations from ISO Certification audit	J. Rodriguez	8/20/18	0032

1.0 Scope

1.1 General

Based on analysis of Access Assembly LLC's business model, interested stakeholders, and in consideration of its products and services provided, and any statutory or regulatory requirements, Access Assembly LLC has determined the scope of the management system as follows:

Manufacturing of Electronic Assemblies and Products, including wire harnesses and cable assemblies.

1.2 Application

The Quality Management System applies to all processes, activities and employees within the company. The facility is located at:

1047 E. High Street
Mundelein IL 60060
United States of America
Phone: 847-894-1047
Fax: 866-908-6325

1.3 Permissible Exclusions

The following clause of ISO 9001: 2015 was determined to not be applicable to Access Assembly:

Clause or Sub-clause	Exclusion	Justification
8.3	Design and Development of Products and Services	Design does not apply to Access Assembly LLC, as Design is not within the scope of this company's services. The customer performs all design development and provides all design specifications.

2.0 Reference Documents.

The following external documents contain provisions which, through reference in this manual, constitute provisions of our QMS:

ISO 9001:20015, Quality management systems – Requirements

- Customer Specific Requirements (see Customer ref# QM02)
- Quality Policy (see QM03)

Appendix A contains a List of Key QMS documents referenced in this manual and defines the key top level processes for implementing our quality policy. Note: documents are referenced throughout this manual only by document number; see Appendix A for complete titles.

3.0 Terms and Definitions.

Our QMS uses the same internationally recognized terms, vocabulary and definitions. Acronyms, terms, vocabulary and definitions unique to our organization, customers, industry and region and referenced throughout our QMS are contained in *Appendix B*, Terms and Definitions.

4.0 Context of the Organization

4.1 Understanding the Organization and Its Context

Access Assembly has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company. This requires understanding internal and external issues that are of concern to Access Assembly and its interested parties (per 4.2 below).

Such issues are documented on the internal and external concerns form and 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 per 4.1 above are identified through an analysis of risks facing Access Assembly 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 also documented on the Internal and External Concerns form and 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

Access Assembly does not currently offer design services, and as such cannot guarantee any item be free from defects inherent in the original design. However, they are looking at offering the services in the future, and are always open to making suggestions based on previous experience, as well as alerting customers to potential problems if they are found throughout the process. Based on an analysis of the above issues of concern, interests of all internal and external stakeholders, and in consideration of its products and services, Access Assembly has determined the scope of the management system as follows:

Our QMS is designed to ensure higher quality electronic products and services, and the highest possible customer satisfaction through a continually improving system of metrics and ideas.

4.4 Quality Management System and its Processes

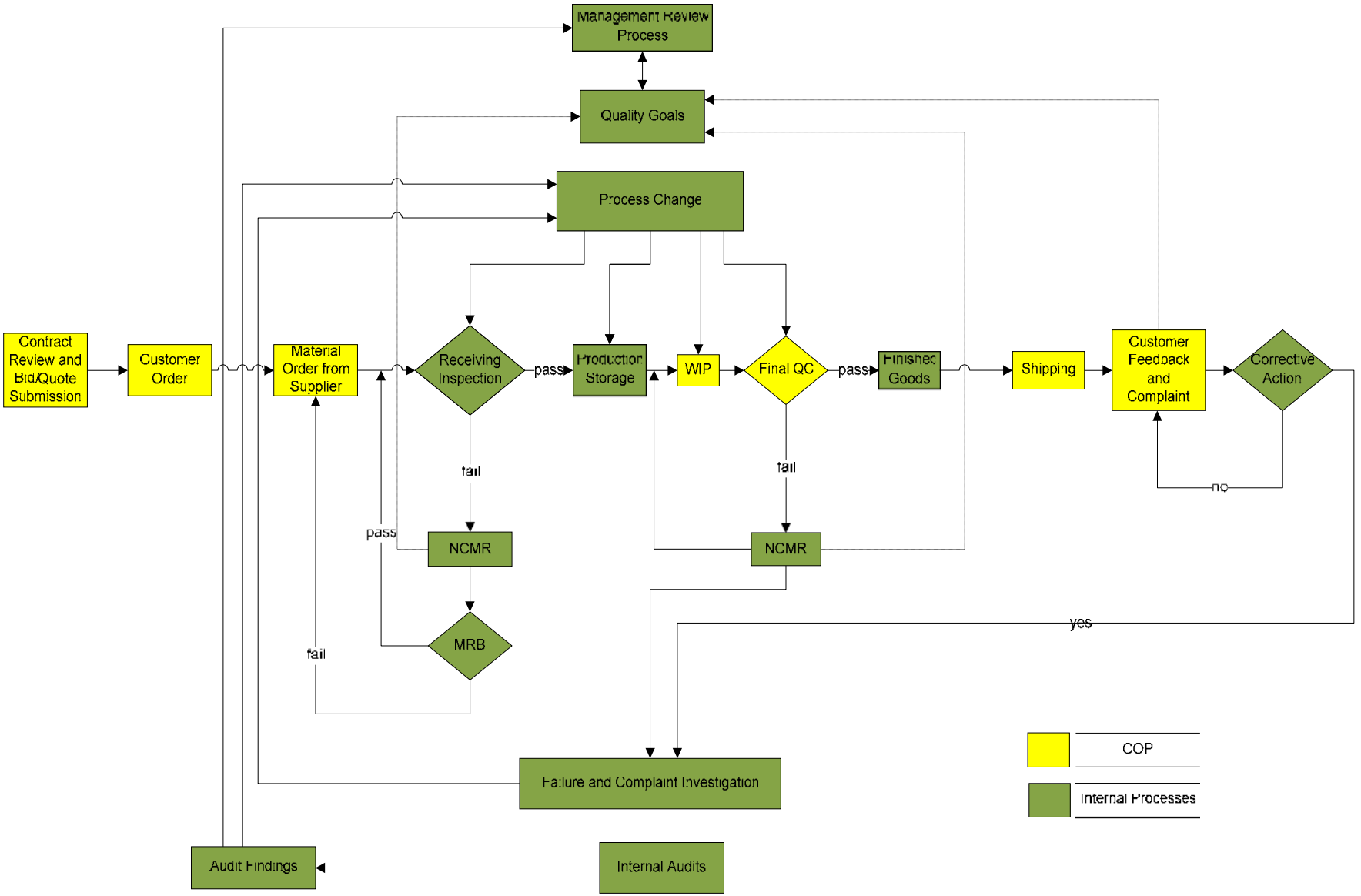
Our QMS is that part of our overall management system which establishes, documents and implements our quality policy, and related processes for providing products and services which meet or exceed customer requirements, and satisfies QMS requirements of *ISO 9001:2015*.

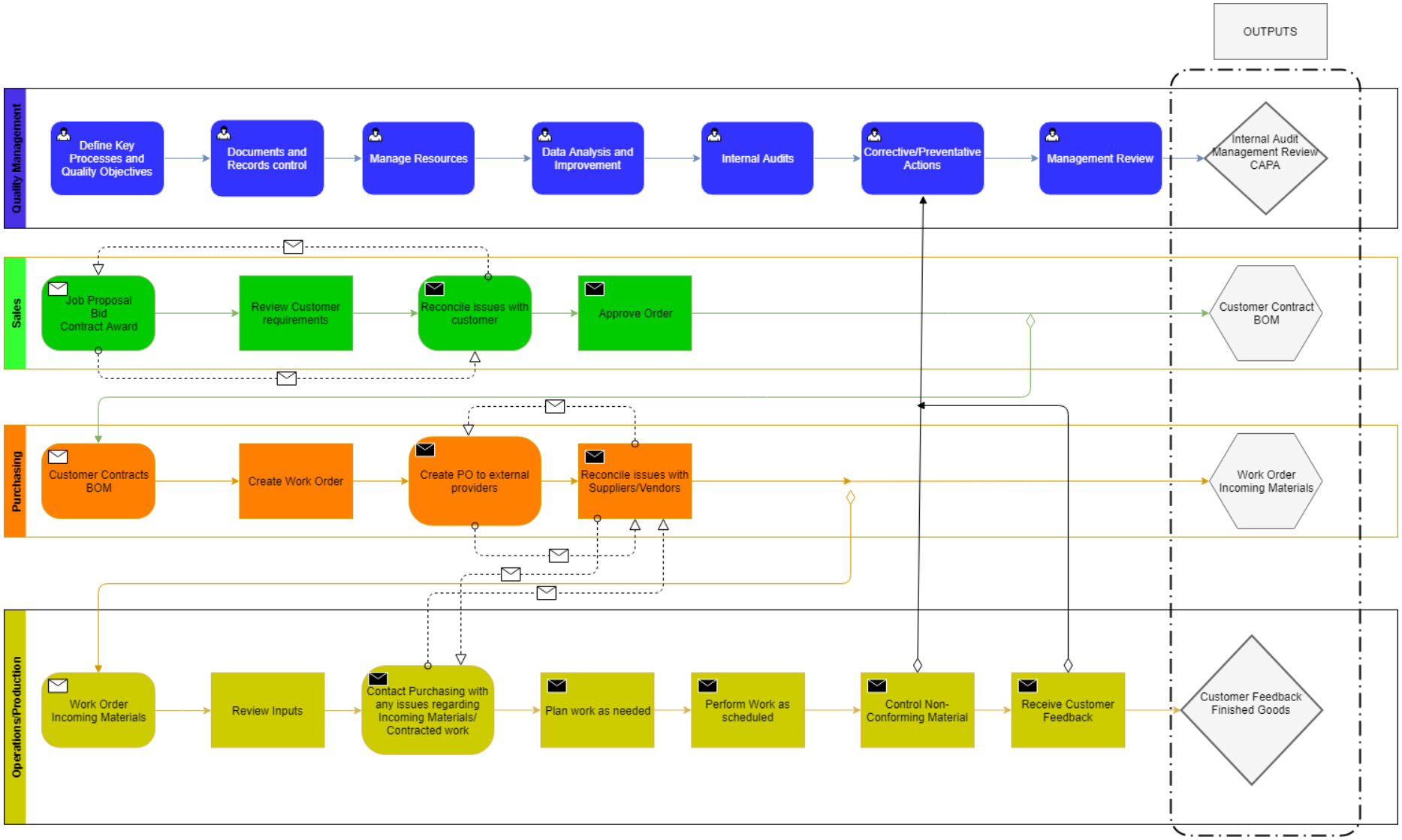
We have adopted the process approach by defining and managing:

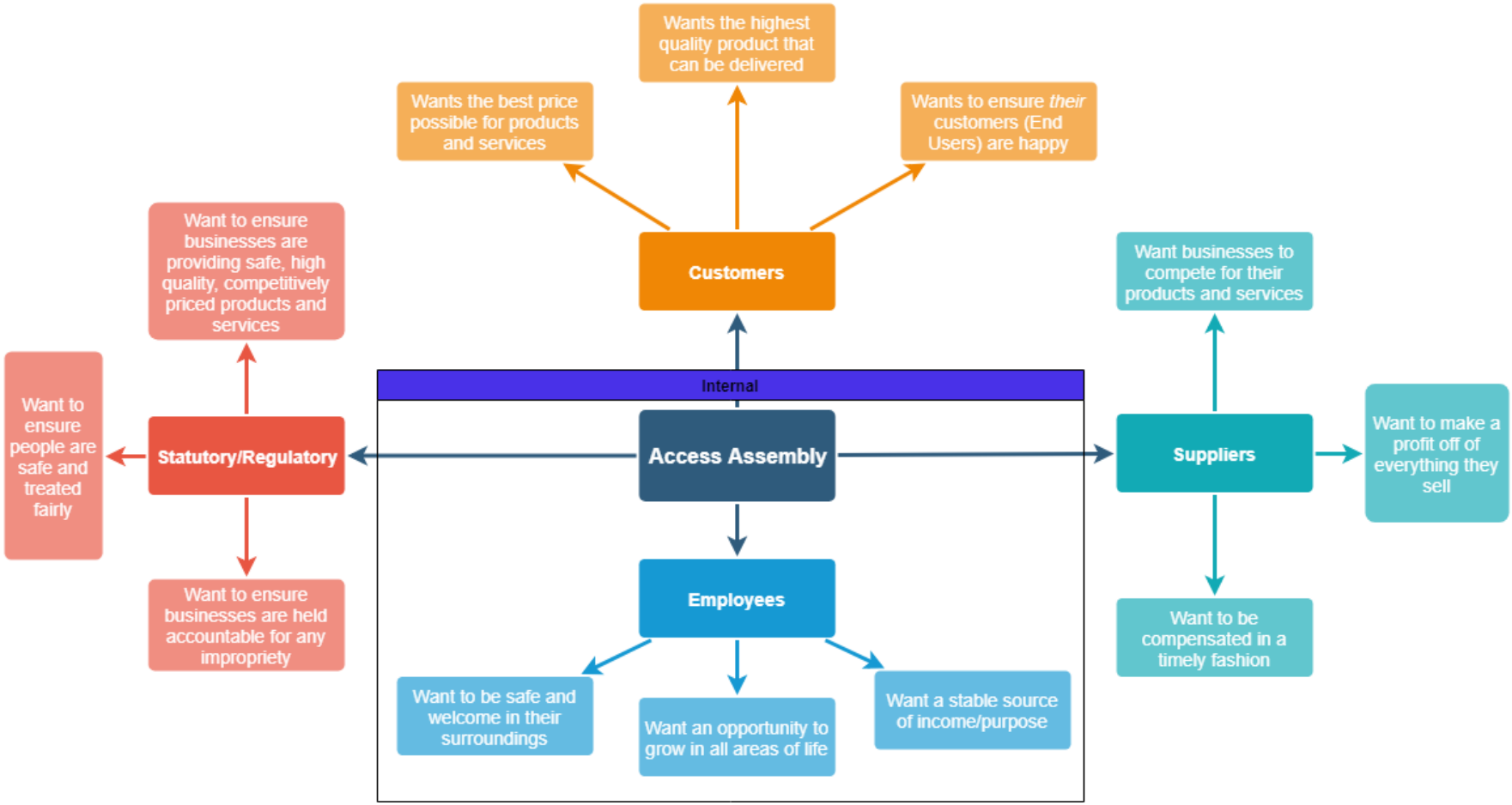
- process inputs, controls, and outputs to ensure desired results are achieved, and
- interfaces between interrelated processes to ensure system effectiveness is achieved.

Our ‘core’ business processes are what we call ‘Customer Oriented Processes’, or COPs, which are in place to meet the specific needs of our external customers, Product Realization processes (i.e. things we ‘do’). The basic sequence and interaction of our COPs is depicted below.

ACCESS ASSEMBLY QUALITY SYSTEM




OUTPUTS
Quality Management
Define Key Processes and Quality Objectives
Documents and Records control
Manage Resources
Data Analysis and Improvement
Internal Audits
Corrective/Preventative Actions
Management Review
Internal Audit Management Review CAPA
Sales
Job Proposal Bid Contract Award
Review Customer requirements
Reconcile issues with customer
Approve Order
Customer Contract BOM
Purchasing
Customer Contracts BOM
Create Work Order
Create PO to external providers
Reconcile issues with Suppliers/Vendors
Work Order Incoming Materials
Operations/Production
Work Order Incoming Materials
Review Inputs
Contact Purchasing with any issues regarding Incoming Materials/ Contracted work
Plan work as needed
Perform Work as scheduled
Control Non-Conforming Material
Receive Customer Feedback
Customer Feedback Finished Goods



Techniques and tools for process management are discussed in *Section 8*.

Specific responsibilities for and the sequence and interaction of our key QMS processes are detailed in Operating Procedures (OPs). *Appendix A* contains a List of Key QMS Documents, including all OPs and other key top level QMS documents.

We also recognize the significant role that subcontractors play in achieving desired results and recognize that we must ensure proper control over outsourced QMS processes (*Section 7.4.1*). Management of outsourced processes is governed by procedures described in documents referenced in applicable OPs. Management of outsourced personnel is governed by procedures described in documents referenced in applicable OPs, except where statutory or regulatory responsibilities are shared between Access Assembly and the Employer of Record where allowed by law.

5.0 Leadership

5.1 Leadership and Commitment

Top management shall demonstrate leadership and commitment with respect to the QMS by:

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

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

c) ensuring the integration of the QMS requirements into the organization's business processes;

d) promoting the use of the process approach and risk-based thinking;

e) ensuring that the resources needed for the QMS are available;

f) communicating the importance of effective Quality management and of conforming to the QMS requirements;

g) ensuring that the QMS achieves its intended results;

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

i) promoting continual improvement;

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

5.1.1 Customer Focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

a) customer 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 (see Section 5.2 and Section 6.0);

c) the focus on enhancing customer satisfaction is maintained (see Section 5.2).

Customer complaints and other customer input/feedback are continually monitored and measured to identify opportunities for improvement.

We continually look for other ways to interact directly with individual customers to ensure a proper focus to their unique needs/expectations is established and maintained: e.g. customer audits, customer visits, trade shows, joint planning sessions, etc.

These customer focused communications and interactions ultimately yield clear, explicit customer requirements and expectations in the form of a contractual agreement or customer order.

5.2 Policy

The Quality Management System (QMS) Policies shall be defined by Top Management with input from the Quality Management Representative. The QMS Policy shall be reviewed at least annually during the Management Review to ensure its adequacy and appropriateness. The QMS Policy shall be communicated to all visitors, contractors and employees upon hire, at least annually and if significant changes to the policy occur.

Our quality policy statement documents and communicates the importance of meeting or exceeding all applicable requirements (including customer, statutory, regulatory and legal requirements) through continual improvement of our processes, products, and services.

We ensure that our quality policy is understood, implemented, and maintained at all levels of the organization through printed distribution of our quality policy statement, and through periodic management review of the quality policy statement and company improvement objectives. In addition, our quality policy and objectives are communicated and deployed throughout the organization through individual performance objectives established and reviewed during employee performance reviews.

5.2.1 Quality policy

It is the policy of Access Assembly LLC to establish and maintain a Quality System that is consistent with and achieves the following goals:

- The Quality System shall be in compliance with all applicable aspects of the current versions of ISO 9001 (Quality systems - Model for quality assurance in design, development, production, installation, and servicing).

- The product received by the customer meets or exceeds all of the customer's expectations, as well as all applicable statutory and regulatory requirements. The product shall: a) Meet or exceed all relevant specifications, both published and internal. b) Be sufficiently durable, that when properly maintained (as described in the relevant operator's manual), it will function properly when called upon to do so.

- The Quality System shall track the numbers of warrantee repairs, set specific goals, and strive to achieve the minimum practical number.

Our quality policy statement indicates our commitment and focuses on what is important to us as an organization: *achieving customer satisfaction*; and it prescribes the method by which we accomplish this: *by continually improving processes, products, and services to ensure they consistently meet or exceed requirements.* Moreover, our quality policy statement acts as a compass in providing the direction and a framework for establishing key company performance measures and related improvement objectives.

We ensure that our quality policy is communicated and understood by the organization through documented training, regular communication, and reinforcement during annual employee performance reviews.

Our quality policy statement is controlled by inclusion in this manual, and along with all policies contained in this manual, is reviewed for continuing suitability during management review

5.3 Organizational roles, responsibilities and authorities

Management shall ensure the availability of resources essential to establish, implement, maintain and improve the QMS. Resources include human resources and specialized skills, organizational infrastructure, technology and financial resources.

Roles, responsibilities and authorities are identified below.

The organization's top management is responsible for ensuring that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. See Organizational Chart in Section 1B and associated job descriptions in Section 2.4.

These responsibilities include:

a. ensuring that an QMS is established, implemented and maintained in accordance with the requirements of the applicable standards,

b. reporting to top management on the performance of the QMS for review, including recommendations for improvement.

c. ensuring that the QMS conforms to the requirements of its applicable International Standard(s);

d. ensuring that the processes are delivering their intended outputs;

e. reporting on the performance of the QMS and on opportunities for improvement, in particular to top management;

f. ensuring the promotion of customer focus throughout the organization;

g. ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

All managers demonstrate their commitment to the development and improvement of the QMS through the provision of necessary resources, through their involvement in the internal audit process, and through their proactive involvement in our continual improvement activities – where emphasis is placed on improving both effectiveness and efficiency of our key QMS processes.

The President of the company sets direction and ensures the success of our business through the clear definition and communication of QMS responsibilities and authorities. Other functions performed by the President include: Quality Assurance (QA), Operations, Financial and Human Resources (HR). The responsibilities, authority and interrelationship of Management and other key personnel or functions, is depicted in our Organization Chart and described in *OP Section 1B*.

- Top Management – The President is ultimately responsible for the quality of Access Assembly LLC's products and services since he controls the systems and processes by which work is accomplished. Top Management is responsible for Business Planning, development and communication of our quality policy, QMS Planning including the establishment and deployment of objectives, the provision of resources needed to implement and improve the QMS and management reviews. Specific requirements are defined in the Procedure Manual as follows: a) OP Section 1B - Management and Organization. b) OP Section 18 - Quality Audits c) OP Section 22 - Training d) Other sections that require personnel for specific functions.
- Management – The manager functions are responsible for execution of the Business Plan and implementation of the policy, processes and systems described in this manual. The manager functions are responsible for planning and controlling QMS processes within its area(s) of responsibility, including the establishment and deployment of operational level objectives, and the provision of resources needed to implement and improve these processes.

  Manager functions also conduct employee performance reviews. Management with responsibility and authority for corrective action are notified promptly of non-conformities. Management ensures that production is staffed with personnel in charge of, or delegated responsibility for product quality.

- Employees - All employees are responsible for the quality of their work and implementation of the policy and procedures applicable to processes they perform. Personnel responsible for product quality have the authority to stop production to correct quality problems. Employees are motivated and empowered to identify and report any known or potential problems and recommend related solutions through internal audits and/or the continual improvement and corrective/preventive action processes.

Detailed responsibilities and authorities for QMS implementation and improvement are contained in lower level documents referenced throughout this manual and other QMS documents including procedures, flow charts, job descriptions, work instructions, etc.

6.0 Planning

6.1 Actions to address risks and opportunities

Access Assembly shall determine the risks and opportunities that need to be addressed to:

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

Access Assembly shall plan:

a) actions to address these risks and opportunities;
b) how to:
    1) integrate and implement the actions into its QMS processes; and
    2) Evaluate the effectiveness of these actions.

Access Assembly reviews risks and opportunities and evaluates their potential consequence or benefit. Risks and opportunities shall be evaluated on the Process Map and the FMEA. Actions taken to address risks shall be proportionate to the potential impact on the conformity of products and services. The relation of Action-to-Impact will be documented using the FMEA.

6.2 Improvement Planning

Management will make certain quality objectives, including those needed to meet requirements for products are established at relevant functions and levels within the organization. Quality objectives are measurable and consistent with the quality policy.

Access Assembly shall consider its technological options and financial, operational and business requirements, and the views of interested parties in setting goals.

Goals shall be measurable and quantitative where appropriate, and amended as necessary when changes are made within the company. Goals and associated action plans, responsibilities, monitoring frequency, necessary resources, due dates and evaluation methods shall be documented on the Objectives, Targets and Programs form.

Our overall quality goal is to achieve our quality policy, and maintain the integrity of and continually improve a QMS compliant with *ISO 9001:2015*. Further, we establish both company and operational level improvement objectives that are measurable and achievable within a defined time period. Company improvement objectives, derived from our Business Plan ref# BP01 and customer goals/targets, are documented on a *090211- Management of Change form/ 090213 Context of the Organization (COTO) worksheet* and reviewed for achievement during management reviews. All managers of key QMS processes monitor and measure performance of processes within their area(s) of responsibility and, where appropriate, establish measurable operational level improvement objectives consistent with our quality policy and company improvement objectives. Operational level improvement objectives are documented on *Process Assessment form-090212* and deployed to individuals or individual work areas and monitored for achievement through employee performance reviews.

Company and operational level improvement objectives are reviewed for consistency, accomplishment and clarity through our management review process and may include any/all of the following possible measures:

- Customer Satisfaction: Operations Manager.
- Supplier Performance: Operations Manager.
- QMS Effectiveness: Operations Manager.
- Overall Operational Efficiency and Manufacturing Process Efficiency: Operations Manager.
- Training Effectiveness and Employee Awareness: Human Resources Functional Officer with input from the Operations Manager.
- Effectiveness of Manufacturing Processes: Operations Manager.
- Product Quality: Quality Manager and/or Operations Manager.

Our top 5 objectives include the following performance criteria on a monthly basis:

1. To reduce non-conformity to 2% or less defects on products shipped to customer, measured in returns vs shipped product;
2. To achieve greater than 95% On-time delivery performance, when conditions can be reasonably accounted for and controlled;
3. To manage and control the facility, processes, quality systems and personnel to consistently and cost effectively produce products that meet customer needs, as well as reduce waste to under 2% of inventory cost. These will be measured as follows:
    - Incoming Inspection: less than 2% errors in receiving
    - WIP: less than 2% defects in processes
    - Final QC: less than 1% errors in Test/Shipping
    - Waste: less than 2% Scrap rate;
4. To be committed to continuous process improvement, consistency and to achieve 100% of Customer Requirements, measured in customer complaints;
5. To conduct our operations in conformance with, or to exceed, all applicable ISO 9001:2015 requirements, with a goal of 0 Major findings in Internal Audits and 5 or less Minor findings. This goal is checked yearly.

6.3 Planning of Changes

Access Assembly determines the need for changes to the quality management system using the COTO worksheet, the changes are carried out in accordance with our quality policy and tracked on the Management of Change Log.

7.0 Support

7.1 Resources

We have determined, and the resources have been provided to, implement and maintain the quality management system and continually improve its effectiveness and enhance customer satisfaction by meeting customer requirements.

The Operations Manager, with input from all responsible staff, ensures, appropriate resources, including trained employees and appropriate equipment, facilities, support services and work environment needed to implement, manage and improve an effective/efficient QMS and enhance customer satisfaction, are identified and provided through our budgeting and other business management processes including but not limited to:

QMS Planning

Human Resource Planning

Plant, Facility, Equipment and other Infrastructure Planning

Work Environment and Safety Planning

Product Realization Planning

Planning of Customer-related Processes

Planning of Purchased Product (Materials, Services and Suppliers)

Production Planning

Measurement Systems Planning

Measurement, Analysis and Improvement Planning

Continual Improvement Planning

The Operations Manager, with input from other responsible staff, monitors and measures overall operational efficiency and provides related input and recommendations that may affect QMS effectiveness to Top Management for review and action.

Specific requirements are defined in the *Procedure Manual* as follows: a) *OP Section 1B* - Management and Organization. b) *OP Section 18*- Quality Audits c) *OP Section 22* - Training d) Other sections that require personnel for specific functions.

7.1.1 General:

Access Assembly determines and provides the resources necessary to:

a) Effectively implement and maintain the QMS and continually improve its effectiveness, and
b) Enhance customer satisfaction by meeting or exceeding all customer requirements.
c) The capabilities of and constraints on existing internal resources
d) What needs to be obtained from external providers.

7.1.2 People

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

7.1.3 Infrastructure

Access Assembly determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

e) The building and workspace;
f) information and communication technology;
g) supporting resources, as required
h) Information and Communication of Process

The Operations Manager has overall responsibility for planning, providing and maintaining the resources needed to achieve product conformance, including buildings, workspace and associated utilities; process equipment (hardware and software); and supporting services (such as internal transportation and material handling systems and communications systems).

The Operations functional manager has overall responsibility for ensuring the Facilities and Equipment Maintenance programs in accordance with *OP Section 3C*; these programs include:

- facilities management, maintenance and repair
- housekeeping/custodial services management
- process equipment management, maintenance and repair
- production tooling management, and
- transportation and material handling equipment management, maintenance and repair.
- Information systems

7.1.4 Environment for the Operation of Processes

We provide job and schedule flexibility, interesting work, and involvement of our employees in an empowered environment of continual improvement. We engender total participation by involving employees in internal audits and improvements activities. The HR functional manager has overall responsibility for identifying, implementing and maintaining effective employee benefit and workforce involvement programs.

Employees are encouraged to identify any factors in their work environment that is negatively affecting themselves and others, and by extension the quality of our products and services. This includes, but is not limited to:

- Social factors (workplace is calm, inviting, and non-discriminatory, etc.);
- Psychological factors (workplace is free of undue stressors, emotionally protective, etc.); and
- Physical factors (adequate lighting, climate controlled, with adequate airflow, etc.)

The Operations Manager has overall responsibility for identifying, implementing and maintaining safety and environmental management systems, processes and controls needed to ensure product conformance and meet customer, statutory or regulatory requirements.

7.2 Monitoring and Measuring of Resources

Access Assembly shall determine and provide 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.

Access Assembly shall ensure that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken and are maintained to ensure their continuing fitness for their purpose.

7.2.1 Measurement Traceability

When measurement traceability is a requirement, or is considered by Access Assembly to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

i) Verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for verification shall be retained as documented information; -OR-
j) Calibrated if a customer, statutory, or regulatory requirement exists for a measurement that is critical to the intended function or design of a particular product;
k) identified in order to determine their status; -AND-
l) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

Access Assembly shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

7.2.2 Organizational knowledge

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

a) internal sources, such as employee knowledge and experience, lessons learned, etc.
b) external sources such as standards, specifications, academia, information gathered from customers or suppliers, etc.

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

When addressing changing needs and trends, Access Assembly Inc shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge. Any knowledge specific to a procedure, process or job shall be noted in said procedure, process or job control; and any update to said documentation shall go through the standard Management of Change procedure noted in OP Section 10: Document Control.

7.3 Competence, Training and Awareness

We determine the necessary competence for personnel performing work affecting conformity to product requirements; where applicable, provide training or take other actions to achieve the necessary competence; evaluate the effectiveness of the actions taken; make certain personnel aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives and maintain records of education, training, skills and experience.

Every task within the QMS may directly or indirectly influence product quality. All Employees are part of the QMS therefore they are the most valuable resource of our company and they are helped to achieve their full potential through continual education and training.

The competency of people assigned responsibilities defined in the QMS is determined on the basis of documented criteria for appropriate education, training, skills, and experience for each required competency or work assignment. The HR functional manager has overall responsibility for administering Access Assembly LLC's Human Resource Management programs in accordance with procedures detailed in *OP Section 22* and the following policies.

Need Determination. We determine competency needs, including employee training and awareness needs, through the following actions:

Top Management identifies emerging competency needs during management reviews. Emergent competency needs are converted into job descriptions for the type and number of positions that need to be filled through external recruitment, internal reassignment/promotion, and/or outsourcing actions.

The HR functional manager, with input from responsible staff, evaluates and qualifies applicants for specific job openings on the basis of documented or demonstrated competencies. Where possible, we help existing employees qualify for new/changed jobs through the provision of appropriate education and training, including on-the- job-training (OJT).

The HR functional manager, with input from responsible staff, establishes and maintains job descriptions for each position held at Access Assembly LLC to document the specific competencies needed to ensure the quality of Access Assembly LLC's products and services.

a) *Provision.* Training needs identified as a result of the need determination activities discussed above are passed on to the HR functional manager for appropriate planning and timely provision.

b) *Effectiveness.* The effectiveness of all actions taken to meet competency needs is evaluated. Training provided is evaluated through immediate feedback from the employee and the manager, officer, or supervisor who identified the training requirement. Training effectiveness is collected and documented by the responsible manager for each training event. The HR functional manager, with input from other responsible staff, monitors and measures the overall effectiveness of training and other actions taken to meet competency needs and provides related recommendations to Top Management for review and action.

c) *Employee Awareness.* We ensure that our employees are aware of customer requirements, the relevance and importance of their activities and how they contribute to the achievement of our quality policy and objectives. This is accomplished through awareness training, employee performance reviews, and employee participation in our internal audit and improvement processes.

d) *Records.* Appropriate records are maintained of education, training, skills and experience. Employee qualification/competency review records and annual performance review results are maintained by the HR functional manager. The Training functional manager maintains records of all training completed.

7.4 Communication

Senior management shall ensure that communication processes are established within the company and with customers, suppliers, contractors and external interested parties.

7.4.1 Internal Communication

The following internal communication topics will be communicated to all employees during the initial QMS Awareness Training and annual refresher training:

- the quality management system and its structure;
- effectiveness of the management system; and
- the importance of meeting customer requirements.

Internal communication shall take place for employees upon hire, at least annually and as significant changes occur within the organization.

We communicate information regarding QMS processes and their effectiveness through documented training, the internal audit process, continual improvement and corrective/preventive action processes, and regular formal and informal communications as follows:

- The Access Assembly Operations Manager posts information on company bulletin board in the facility to convey information regarding customer requirements, and the status and importance of quality activities. Internal audits are also used to reinforce or communicate appropriate information to employees.
- The Safety Manager posts information on safety bulletin boards throughout the facility to convey information regarding the status of the Safety and Environmental Management Program, and related statutory/regulatory requirements.

- The HR Manager posts information on company bulletin board in the facility to convey information regarding employee benefits, programs, involvement opportunities, and applicable statutory/regulatory requirements.

Manager functions are responsible for establishing internal communications as needed to convey to their employees the relevance and importance of their activities; typically this information is conveyed through production meetings. Communications regarding how employees contribute to the achievement of objectives is also conveyed and reinforced during employee performance reviews.

7.4.2 Customer / Interested Party Communication

We communicate with our customers and interested parties either verbally, fax and/or email concerning product information, contracts, including amendments and customer feedback. All communication is either stored in the job files and/or in our computer database.

7.4.3 Supplier Communication

Suppliers shall have access to the Quality Policy prior to use. For suppliers of raw materials, they shall be evaluated at least annually. If supplier is approved in accordance with the Supplier Evaluation form, they will be approved and added to the Approved Supplier List.

Top management shall review the performance during the annual review to determine if status of supplier is sufficient to remain on the approved vendor list.

7.5 Document and Recordkeeping Controls

This manual contains documented statements of our quality policy and quality objectives and references documented procedures required by *ISO 9001:2015* and other documents needed to ensure effective planning, operation and control of our key QMS processes.

The level and type of QMS documentation established for our business is continually reviewed to ensure it remains appropriate for the complexity and interaction of our processes and the competence of the company's employees. QMS documents and data may be in hard copy or electronic media.

The ACCESS ASSEMBLY quality system consists of three levels of documentation as follows:

a) Quality Manual: This *Quality Manual* contains a general description and definition of the quality system.

b) Procedure Manual: The *Procedure Manual* contains the specific procedural (OPs) methods for carrying out the activities required by the *Quality Manual*.

c) Specific Procedures: There are specific procedures that contain instructions for performing specific tasks. They include, but are not limited to the following types of documents:

   1) Incoming inspection procedures for each specific component.

   2) Final test and inspection procedures for specific finished devices.

   3) Calibration procedures for specific pieces of test equipment.

   4) Customer Requirements, Drawings of specific components.

QMS documentation also includes other internal and external documents and data needed to manage, perform or verify work affecting product quality.

We use customer feedback and internal audit reviews to aid in the development, assessment and/or improvement of processes defined in OPs. We also issue and control work instructions, job descriptions, and other internal and external documents and data as appropriate and needed to effectively manage our QMS.

7.5.1 Quality manual

This manual is that part of our QMS that defines the scope of our QMS and documents the policy, procedures and processes needed to implement our quality policy and achieve our quality objectives. This manual also documents justifications for exclusions from *ISO 9001:2015* requirements and defines the overall sequence of and interaction between our key QMS processes.

7.5.2 Control of documents

The Quality Manager or Operations Manager shall establish, implement, and maintain the procedures described in Sections 4.2.1(a,b), and 4.2.1 (c)(1,2,3,4). The Operations Manager shall establish, implement, and maintain the remaining procedures described in Section 4.2.1. The overall responsibility is to ensure that all QMS documents, including forms used to create quality records, are controlled per procedure detailed in *OP Section 10, Document Control* and summarized below:

a) approve documents for adequacy prior to issue.

b) review, update as necessary and re-approve documents.

c) identify the current revision status of documents.

d) ensure that relevant versions of applicable documents are available at points of use.

e) ensure that documents remain legible, readily identifiable and retrievable.

f) ensure that documents of external origin (including customer engineering standards/specifications) are identified and their distribution controlled.

g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

All documents will be approved as specified in *OP Section 10, Document Control* prior to being issued. The mechanism for issuing documents is specified in *OP Section 10*. Each department manager shall be responsible for determining what documents are required in his department, and ordering (controlled) copies of those documents from the Document Control Clerk or Operations Manager. In accordance with *OP Section 10*, the Document Control Clerk or the Operations Manager shall ensure that a copy of each revised document is distributed to all individuals who have a controlled copy.

Changes to documents shall be reviewed and approved by the same functions/organizations that performed the original review and approval. The mechanism for making, reviewing, and approving changes to documents are described in the *OP Section 10.*

Where practical, the nature of the change shall be described in the document. In other cases, the nature of the change shall be described on the change order form or on documents attached to the change order.

Requirements for the establishment and maintenance of Master Lists of internal and external QMS documents are defined in *OP Section 10, Document Control.*

7.5.3 Control of records

The Quality Manager or the Operations Manager has overall responsibility for ensuring that all records required for the QMS (including customer-specified records) are controlled and maintained to provide evidence of conformance to requirements and effective operation of the QMS. Records are retained for a period defined by the customer, applicable regulatory requirements and/or Access Assembly LLC management, as applicable, and then disposed of in accordance with applicable requirements. Records may be in the form of hard copy or electronic media. *OPs Sections 23 and 23A,* details procedures necessary to control QMS records that, at a minimum, are prepared to document:

a) results of processes performed, including identification of the individual performing the activity.

b) product/process evaluation/acceptance criteria.

c) procedures, drawings or instructions used to perform an activity, including revision or date of document.

d) identification of material, parts, or equipment used in the making of the product.

e) personnel, material or equipment qualifications.

ACCESS ASSEMBLY products definable life expectancy complies with the agreed upon requirements identified by the customer.

- *Inquiries* are handled by our Operations Manager. Operations Manager provides *technical assistance* and related information as needed.

- We pay particular attention to customer feedback, including *customer complaints* and customer satisfaction. We encourage and address customer feedback, particularly customer complaints. *Customer satisfaction* is evaluated on an on-going basis.

8.0 Operational Planning and Control

8.1 Operational Planning and Control

Access Assembly has procedures to maintain risk control over those operations and activities that are associated with Quality. These procedures also provide controls related to customers, suppliers and those personnel working on the behalf of Access Assembly, including contractor activities and temporary personnel.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

To provide communications with the customers in relations to

a) Product information,

b) Enquiries, contracts or order handling, including amendments

c) Customer feedback, including customer complaints. The arrangements described here have been put into place.

Customers are provided information for the following 'key' customer contact personnel: President & Operations Manager.

Customer communications are established through a variety of channels:

- Operations functional manager provides *product information* directly to customers including verbal and printed information (digital and written) on our assembling services as well as customized information for unique customer applications.

8.2.2 Determining the Requirements Related to Products and Services

Our QMS identifies, plans for and documents our product and service realization processes to ensure consistency with all applicable requirements, including customer requirements and related quality objectives and requirements for specific products/services, and any/all applicable statutory/legal requirements. The outputs of product/service realization planning include the specific methods, facilities, and equipment, people and materials/support services needed to achieve all desired results for a particular product, service, or contract.

Should requirements not adequately address the standard job pack documentation/data, or as required by the customer, the Operations Manager has overall responsibility for developing and implementing a quality control plan to address additional requirements or controls needed to verify work for the specific process, product or contract in question; see *OP Section 12*.

The outputs of quality planning (i.e. job packs, control plans, etc.) are carried out in accordance with planned monitoring and measurement activities, which may also include the use of appropriate statistical techniques.

Sales functional personnel or Operations Manager generate quotes/bids and negotiate final contracts/orders; Contracting functional Manager receives customer orders for standard items or for items included previously bid or negotiated. Requirements for most major customers are identified in contracts documented and periodically reviewed. In other cases, a customer order constitutes a contract, and we ensure that the customer's requirements are clearly identified and confirmed prior to acceptance. *OPs Section 20 & 21* defines our process for determining product related requirements, including:

Product requirements specified by the customer, including the requirements for availability, delivery and post-delivery provided as part of the customer contract or purchase order.

Product requirements not specified by the customer but necessary for intended or specified use and obligations related to product, including regulatory and legal requirements; this may include recycling, environmental impact, and characteristics identified as a result of Access Assembly LLC's knowledge of the product and related production processes.

All applicable government, safety, and environmental regulations applied to the acquisition, storage, handling, recycling, elimination or disposal of materials.

8.2.3 Review of Requirements Related to Products and Services

Contracting functional personnel or Operations Manager review customer requirements identified during the determination process to ensure that they are clearly stated, understood, and recorded. Our process for reviewing all applicable requirements is defined in *OPs Section 20 & 21* to ensure:

d) All applicable product requirements are defined, understood and confirmed with the customer prior to acceptance. Manufacturing feasibility of proposed (new or changed) products is investigated, confirmed and documented prior to making a commitment to supply.
e) Contract or order requirements differing from those previously expressed are resolved
f) Ensure Access Assembly LLC has the ability to meet the defined requirements.
g) Statutory and regulatory requirements applicable to the products and services rendered are met

Records of the review and actions resulting from the review are maintained.

The Operations Manager obtains necessary customer authorizations to waive formal reviews where it is deemed impractical for each order.

The Operations Manager investigates, confirms and documents the manufacturing feasibility of proposed products or services in accordance with customer-specific requirements.

Where product requirements are changed, we ensure relevant documents are amended and relevant personnel are made aware of the changed requirements; *OP Section 10*.

8.2.4 Changes to Requirements for Products and Services

Access Assembly updates all relevant requirements and documents when the requirements are changed, and ensures that all appropriate staff are notified; see the documented procedure Management of Change.

8.3 Design and Development

Design does not apply to Access Assembly LLC, as Design is not within the scope of this company's services. The customer provides all design specifications.

8.4 Control of Externally Provided Processes, Products and Services

Achieving our quality policy "to meet or exceed customer requirements" requires that we determine, understand, and consistently meet or exceed our customers' requirements and expectations, and that we establish effective communication systems with our customers with regards to product information, inquiries, contract or order handling and related changes, and customer feedback, including complaints. These efforts are described below. The Operations Manager has overall responsibility for developing and implementing effective customer-related processes in accordance with the policies in this section, International Standards, and statutory and regulatory requirements.

NOTE: Access Assembly does not currently contract external providers to produce or handle products, nor perform services directly for our customer(s). As such, there is currently no provision specifically controlling for this instance, as laid out in ISO 9001:2015 Rev E; Clause 8.4.1 (b). If this situation changes in the future, all process are to be controlled as if supplied internally as laid out in QM01 and all other applicable procedures, until such a time that a specific control can be devised and implemented.

8.4.1 Purchasing

We work in partnership with our suppliers to ensure that purchased products and services meet all applicable requirements. The processes applicable to the planning, acquisition and verification of all products and services that affect customer requirements (such as subassembly, sequencing, sorting, rework and calibration services) are defined in *OPs Section 7A, 7B, 7C, 7D, 7F, and 7G* in accordance with the policies outlined in this section.

8.4.2 Purchasing process

The type and extent of control applied to our suppliers and purchased product is dependent upon the effect on subsequent realization processes and their output, as well as consideration of other characteristics including: the type of product; the potential impact of the product on our processes, products, or services; the results of supplier evaluations; and past performance.

Purchased products are verified to ensure conformity to specified purchase requirements.

OP Section 7B identifies responsible functions for defining and documenting the supplier approval process, including criteria for selection, the extent of control to be exercised and periodic evaluation. Suppliers are evaluated and selected based on their ability to supply products or services in accordance with our requirements.

Where specified (by contract, customer engineering drawing, or specification) we purchase products, materials or services from customer-approved sources.

A master list of approved suppliers is maintained to ensure we only purchase product from Access Assembly LLC qualified sources or customer-approved sources. The results of evaluations and follow/up actions are recorded.

> *Supplier performance is monitored per OP Section 7B through one or more of the following indicators: delivered product quality; customer disruptions including field returns; delivery schedule performance (including incidents of premium freight); and special status customer notifications related to quality or delivery issues.*

8.4.3 Purchasing information

Adequacy of specified purchase requirements prior to communication to the supplier is ensured per procedures defined in *OP Section 7B* and the following policies:

Purchasing information communicated to our suppliers contains the appropriate data needed to clearly and fully describe requirements for purchased materials and services; including, where appropriate, requirements for approval/qualification of product, procedures, processes/systems, equipment; qualification of personnel; and quality management system requirements.

8.4.4 Verification of purchased product

The Quality Manager has overall responsibility for ensuring the quality of purchased products using one or more of the following methods: receipt and evaluation of statistical data; receiving inspection and/or testing (such as sampling based on performance); second or third party audits of supplier sites (when coupled with records of acceptable delivered product quality); part evaluation by a designated laboratory; and/or another method agreed with the customer.

All requirements for approval of purchased product and/or supplier procedures, processes, equipment, personnel, and/or quality systems are reviewed for adequacy prior to communication to the supplier.

As applicable, the Quality Manager documents and communicates the intended verification arrangements and method of product release related to verification activities performed at our suppliers' premises.

8.4.5 Type and extent of control

The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers. This shall be completed as part of the supplier evaluation process.

8.4.5 Information for external providers

Access Assembly shall ensure the adequacy of requirements prior to their communication to the external provider.

Access Assembly shall communicate to external providers its requirements for:

a) the processes, products and services to be provided;
b) the approval of:
   1) products and services;
   2) methods, processes and equipment;
   3) the release of products and services;
c) competence, including any required qualification of persons;
d) the external providers' interactions with the organization;
e) control and monitoring of the external providers' performance to be applied by the organization;
f) verification of validation activities that the organization, or its customer, intends to perform at the external providers' premises.

8.5 Production and Service Provision

8.5.1 Control of production and service provision

We utilize a process-focused approach to plan and control operations and support services related to production. The customer provides all design specifications and provides service provision for the completed product. Our initial focus is to assure the quality of process inputs - that is, employees, material, facilities and equipment, and methods. Employees must be equipped to perform the process properly through appropriate training. Material must meet specified requirements and be properly identified, stored, and issued. Equipment and facilities must be adequate, accurate, available and properly utilized.

> *Work instructions and/or drawings must be current and correct. Methods must be appropriate and proven capable of accomplishing the desired results. The appropriateness of all these fundamental process inputs must be assured, and processes must be measured, monitored and controlled to assure effectiveness and/or to identify opportunities for improvement.*

The Operations Manager ensures that production jobs are planned, scheduled, and carried out in accordance with procedures detailed in *OPs Section 12 and 12A* as summarized below:

a) *Information.* The Operations Manager, ensures that all appropriate information including final product specifications, raw material characteristics and the required product parameters, is provided to production personnel throughout the production process. Such information is provided through job schedules/plans, production meetings, work instructions posted in areas where they are needed, and/or through job specific information included in individual job packs (including control plans, where applicable).
b) *Work Instructions*. The necessity for and required detail of work instructions is dependent upon the knowledge, skills, and abilities of our employees and the complexity of the work process they are assigned to perform. Production functional manager identifies critical production work steps in process sheets included in the job pack or other information

included in work instructions posted in areas where they are needed. Criteria for workmanship shall be specified in the clearest practical manner.

c) *Equipment.* The Operations Manager ensures the suitability and availability of all equipment, facilities and tooling used for production operations.

d) *Monitoring and Measurement Devices*. The Quality Manager or the Operations Manager ensures that monitoring and measurement devices capable of meeting our measurement requirements are available for use during production.

e) *Monitoring Activities*. The Production functional Manager ensures that production personnel monitor the quality of their own work and understand the procedures for reporting related problems and/or suspected nonconforming conditions; *OPs Section 12 & 12A.* The Quality Manager or Operations Manager is responsible for planning and implementing in-process inspections needed to ensure process control and product quality.

f) *Release, Delivery, and Post-Delivery Processes.* Release of product is dependent on its compliance with all technical specifications and its ability to meet additional customer requirements including packaging, shipping, and delivery, as identified in the contract or order. The Operations Manager ensures that records of product approval are maintained and clearly indicate the authorizing employee.

The Operations Manager periodically reviews operational data as well as progress towards achievement of company product performance objectives and provides related recommendations for review by Top Management.

We define processes in which results cannot be verified by subsequent monitoring or measurement as "Special Processes"; this includes any processes where deficiencies may become apparent only after the product is in use or the service has been delivered. The Production functional Manager has overall responsibility for ensuring 'Special Processes" are validated in accordance with procedures detailed in *OP Section 26- Job Setup Verification*. As applicable, arrangements are established for:

a) defining criteria for review and approval of the processes;

b) approval of equipment and qualification of personnel;

c) use of specific methods and procedures;

d) requirements for records.

8.5.2 Identification and traceability

The Quality Manager or Operations Manager has overall responsibility for establishing and maintaining product identification throughout all stages of production and delivery in accordance with procedures defined in

a) During receipt and incoming inspection – *OP Section 7C*

b) While in the stock room – *OP Section 7D*

c) Through the manufacturing process – *OP Section 12*

d) After completion of the manufacturing process – *OP Section 13*

Where product traceability is a customer-specified requirement, appropriate controls and records are established and maintained.

We establish and maintain product monitoring and measurement status through the use of both physical identification tags/labels and electronic records. Additionally, physical location in clearly designated hold area is an indicator of product status; however, physical location in production process areas may serve as an indicator of product status only where product identification and inspection status is inherently obvious. The Operations Manager ensures that all incoming, in-process, and final product is suitably identified and the current status is appropriately tracked and displayed in accordance with procedures detailed in *OP Section 19*.

Where contractually required, the Quality Manager plans for, establishes and maintains appropriate traceability records in accordance with customer requirement. At a minimum, where products are made in lots or batches we identify and record a unique lot or batch number and related information *OP Section 7F*.

8.5.3 Customer property

Customer property includes customer-owned material, tools (including returnable packaging), tooling (including test/inspection tooling and equipment), and intellectual property. We identify, verify, protect and maintain customer property provided for use or incorporation into the product, by applying the same process controls as we do to purchased product (*QMS Section 7.4*).

> *Whenever customer-specified requirements for property management are beyond the control or capability of our established QMS, the Quality Manager or Operations Manager has overall responsibility for planning, documenting and communicating such requirements to all appropriate personnel as a part of product quality planning; QMS Section 7.1.*

The Quality Manager or Operations Manager ensures that lost, damaged, unsuitable or unusable customer property is recorded and immediately reported to the customer

8.5.4 Preservation of product

The Operations Manager has overall responsibility for establishing and implementing a material management system to ensure product conformity is preserved during internal processing and delivery to the intended destination. This system, defined in *OPs Section 7C, 7D, 13, 24 and 31* includes the handling, storage, packaging, delivery, and protection of final product as well as raw materials and in-process constituents of the final product, to ensure:

- Components and products are handled and stored in a manner that prevents damage or deterioration pending use or delivery.
- Each department ensures controls are implemented to prevent mixing conforming and non-conforming materials as outlined in OP Section 31.
- While ACCESS ASSEMBLY LLC products are not subject to damage or deterioration by most reasonably anticipated types of handling; many components and assemblies are static sensitive.

The Electrostatic Discharge Control procedures specified by *OP Section 17* shall be applied as required.

- Packing ensures specified or original manufacturing packaging is utilized.
- There shall be a designated Finished Goods Storage Area, designed to minimize any likelihood of damage to finished product.
- All components and products are suitably packed to prevent deterioration or damage during storage and delivery, as outlined in OP Section 24.

In order to detect deterioration, the condition of stock is periodically assessed. Further, obsolete product (including expired, age dated material, e.g.), and unidentified or suspect stock is controlled as nonconforming product.

8.5.5 Post-delivery activities

Access Assembly offers a warranty on all products and services rendered as required by statute and regulation. In the event of a customer receiving non-conforming material that they wish to have reworked or replaced, they must notify the Quality Manager. The Quality Manager will then follow the procedure(s) laid out in OP Sec 15.A Complaint Handling and or Section 31 Non-conforming Material as appropriate.

8.5.6 Control of changes

Access Assembly shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

Access Assembly shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of products and services

Our quality management system is monitored daily and also through our internal audit program. Our system demonstrates the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

We monitor and measure the characteristics of the product to verify product is correct. Receiving, in-process and final inspections are completed. Evidence of conformity with the acceptance criteria shall be maintained. Records of person(s) authorizing release of product will be maintained. Product is not released until all planned arrangements have been met. If there is a deviation it must be approved by the customer and recorded in the job file and/or in our computer database.

8.7 Control of Nonconforming Product

The Quality Manager has overall responsibility for implementing an effective process for identifying, documenting, segregating, evaluating, and disposing of nonconforming product. Personnel responsible for product quality have the authority to stop production to correct quality problems in accordance with *OP Section 31*; related procedures are summarized below:

Identification. Identification of nonconforming product originates from inspection, internal testing, product audits or customer complaints. Employees clearly mark or otherwise identify nonconforming product or suspect material. Product with unidentified or suspect status is classified and processed as nonconforming.

Documentation. The Quality Manager or authorized Quality Control personnel enter the nonconformance into the corrective action system identifying the nonconforming product and lot number if applicable, description of nonconformance, and location where the nonconforming product is being held pending further review or disposition.

Segregation. Nonconforming product is segregated pending evaluation and disposition.

Evaluation. Authorized Quality Control personnel perform the initial evaluation of nonconforming product in accordance with approved test and inspection procedures. Where needed, Production and other technical personnel (including the customer) may become involved in the evaluation and recommendation for disposition.

Disposition. The results of the evaluation and resultant disposition determinations are documented. Dispositions resulting from the evaluation of nonconforming product may include: rework to meet specified requirements; re-grade for an alternative application; use as is (under customer concession or other required approval authority); obtain (from relevant authority) a waiver or deviation from requirements; return to supplier; scrap or other disposal. Reworked nonconforming product is re-verified after correction to demonstrate conformity to original requirements.

Operations Manager notifies the customer immediately upon discovering that nonconforming product has been shipped. In the event nonconforming product is detected after delivery or use has started, the Quality Manager or Operations Manager notifies the customer and initiates action appropriate to the effects, or potential effects, of the nonconformity. Where appropriate, product recall is initiated based on trace and recall data and records.

Where required, the Operational Manager obtains a customer concession or deviation permit prior to further processing whenever the product or product realization process is different from that which is currently approved.

8.8 Control of Monitoring and Measuring Equipment

The Quality Manager or Operations Manager, is responsible for establishing and maintaining an effective system for identifying, selecting and controlling the use of monitoring and measuring equipment used to provide evidence of product conformance to established requirements. These controls, defined in *OP Section 3C* apply to Access Assembly LLC owned, customer-owned and employee-owned equipment.

Our customer provides the measurements to be made and the accuracy required to assure conformity of our product to specified requirements. We identify and select monitoring and measuring equipment and verify their capability of meeting such requirements prior to use, when this equipment is not provided by the customer.

Monitoring and measuring equipment is used and controlled in a manner that ensures continuing relevance and efficacy; this includes ensuring that the environmental conditions are suitable for the calibration, inspections, measurements and tests being carried out. We also define the processes employed for the on-going calibration, control and maintenance of monitoring and measuring equipment including their identification, location, frequency/method of checks, uses/acceptance criteria and the action to be taken when results are unsatisfactory.

a) All monitoring and measuring equipment that can affect product quality is identified and calibrated at prescribed intervals against certified equipment having a known valid relationship to internationally or nationally known standards. Where no such standards exist, the basis used for calibration is documented. If Access Assembly LLC does not have an internal laboratory facility and therefore cannot perform all required inspections, tests and/or calibrations; accordingly, than these processes will be contracted to external laboratories used for inspection, test or calibration services, qualified and monitored.
b) When monitoring and measuring equipment is found to be out of calibration (or when calibration status is not known), they are adjusted or re-adjusted as necessary and the validity of previous measuring results is documented; actions taken are documented, including appropriate corrective actions to remedy the situation and preclude its recurrence.
c) Appropriate calibration records are maintained to document results of calibration activities and suitable indicators are used to show current calibration status. A number or other identifier is used to provide traceability to the equipment calibration record
d) All monitoring and measuring devices are safeguarded from adjustment that would invalidate the calibration.

e) All monitoring and measuring equipment is handled, maintained and stored in a manner that ensures accuracy and fitness for use is maintained.

9.0 Performance Evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

This section describes how we define, plan, and implement the monitoring, measurement, analysis and improvement activities needed to assure product and QMS conformity and achieve continual QMS improvement. These activities include assessment of customer satisfaction, conduct of internal audits, and monitoring and measurement for products and processes.

The Quality Manager or Operations Manager ensures that statistical tools used to monitor QMS processes are identified during quality planning and included in control plans, as applicable. Statistical techniques for on-going process control and improvement are established per *OP Section 32* and applicable customer specific requirements documents (QM02 and QM03).

Employees utilizing statistical tools to manage, verify or perform work will attend an overview on basic concepts to ensure they are understood and properly utilized throughout the organization.

9.1.2 Customer Satisfaction

Customers are the reason we exist and drive our quality policy “to meet or exceed customer requirements.” The Operations Manager has overall responsibility for identifying and reviewing customer requirements and for monitoring and measuring customer satisfaction per procedures contained in *OP Section 15A*, summarized as follows:

Data collected by customer contact personnel during routine communications provide our primary basis for assessing customer satisfaction. Sales functional manager utilizes a simple customer satisfaction and opinion survey to ascertain the customer’s overall perception of how well we are meeting their requirements and to learn about opportunities for improvement (if any).

Customer complaints (whether received in writing, verbally or electronically) are immediately forwarded to appropriate Sales functional manager or Operations Manager for action. Customer complaints are documented and monitored through resolution through our continual improvement system.

Customer survey data along with other customer feedback (including written or verbal complaints and information) is reviewed by Sales functional manager or Operations Manager to initiate any improvement or corrective/preventive actions needed.

The Sales functional Manager or Operations Manager periodically reviews customer satisfaction survey data and other customer feedback (including complaints), as well as progress towards achievement of company customer satisfaction improvement objectives and provides related recommendations for review by Top Management.

9.1.3 Analysis of data

Top Management and other officers, managers and supervisors collect and analyze data using appropriate statistical techniques to determine the suitability and effectiveness of key QMS processes applicable to their area(s) of responsibility and to identify opportunities for improvement. At a minimum, data is analyzed to assess achievement of the company quality objectives.

A process is effective if desired results are achieved. Effectiveness can be measured in terms of product quality, process accuracy, delivery/schedule performance, cost/budget performance, employee/function performance against established objectives, and/or customer satisfaction.

A process is efficient when resource utilization is optimal. Efficiency can be measured in terms of total resource utilization, productivity indicators, and or the cost of poor quality (such as waste/rework costs or hours).

Regularly Top Management and other key personnel, performs a self-assessment to identify current strengths and weaknesses, and to identify opportunities for improvement, and provide related recommendation to Top Management through our management review process.

9.1.3.1 Monitoring and measurement of processes

We apply suitable methods for monitoring and measuring all QMS processes. QMS processes are documented, measured, controlled and evaluated in relation to the impact each process has on the overall effectiveness of the QMS and the impact they have on our ability to meet product requirements. We ensure they are effective (i.e. achieve desired results) and if needed, to identify opportunities for improvement. At a minimum, managers with overall responsibility for carrying out a QMS process, analyzes process performance and takes appropriate improvement, corrective or preventive action.

We conduct process oriented internal audits to verify QMS process conformance and identify opportunities for improvement. Significant process events, such as tool change or machine repair are recorded. Production personnel follow documented reaction plans when processes become unstable or no longer capable. As required, the corrective action plan is reviewed with and approved by the customer.

9.1.3.2 Monitoring and measurement of product

The Quality Manager or Operations Manager has overall responsibility for planning and implementing inspection and test activities needed to verify product requirements are met at appropriate stages of the product realization process in accordance with the applicable control plan. When selecting product parameters to monitor compliance to internal and external requirements, product characteristics are determined leading to the types of measurement, suitable measurement means, and the required capability and inspection/test skills needed.

The scope of our product monitoring and measurement system includes receiving inspection, job set up verification, in-process inspection, and final inspection and test.

Receiving Inspection. Incoming product is not used or processed until it has been inspected or otherwise verified as conforming to specified requirements in accordance with the control plan and/or documented procedures. Methods used to verify incoming product may include: receipt and evaluation of statistical data by the supplier; formal receiving inspection and/or test (*OP Section 7C*), evaluation by accredited laboratories; or source inspections.

Job Set Up Verification. Job set ups are verified per procedures defined in *OP Section 26* prior to commencing each new production run and/or when process changes are made.

In-process Inspection. Formal in-process inspections are performed by Quality Functional Manager in accordance with the control plan and *OPs Section 7D and 12*.

Final Inspection and Test. All finished products and completed services are verified by final inspections/tests specified in the control plan and *OP Section 13*.

> ***Release****. Products are not released for further processing or delivery until we have objective evidence that all requirements have been met.*

Evidence of Conformity**.** Inspection records are maintained for a minimum of three years. (*Document Control OP Section 10*). These records include final inspection authority and identify and confirm that all critical parameters are in accordance with established requirements and specifications. Additionally, product samples are stored for a time period as defined in *OP Section 11*.

Product Release and Delivery. Product is not released or delivered until all planned inspections have been completed, and records have been maintained providing evidence of conformity with acceptance criteria and identifying the person(s) authorizing release.

Exceptions: In rare cases (due to customer demands and/or production emergencies) unverified product may be released or delivered **under controlled conditions approved by the customer**. Nonconforming (or suspect) product is identified and controlled to prevent its inadvertent use; *QMS Section 8.3*.

9.2 Internal audit

Internal audit results are critical inputs to aid in assessing the effectiveness of our QMS, in identifying opportunities for improvement, and in promoting awareness of customer requirements and effectiveness of the QMS to our workforce.

We conduct QMS audits to determine conformity to *ISO 9001:20015* and any additional QMS requirements that may apply. Our overall measure of QMS effectiveness is the absence of repeat problems/findings, as an indicator that our QMS was effective in eliminating the cause of such problems.

Full system Internal audits are conducted at least annualy. Each of our key QMS processes, with a special emphasis on our ‘core’ customer oriented processes (*COP*) and our unique product realization processes is reviewed to determine effectiveness. The schedule is updated on the basis of status and importance of the activity to be audited and previous audit results.

The QMS process, function or quality system element under review is effective if it is achieving the desired results or established objectives; *QMS Section 5.4.1.* In addition, employee involvement in identifying process effectiveness or efficiency improvements is actively sought during internal audits. Internal audit results are used to determine the scope, nature and frequency of future internal audits of processes, products, functions or quality system elements where ineffectiveness or inefficiency is most likely to be found.

The Quality Assurance Manager or Operations Manager has overall responsibility for managing the internal audit process in accordance with *OP Section 18* as summarized below:

Audits are carried out by qualified personnel who do not have direct responsibility for the process being audited. Auditors record audit results and submit findings to management personnel with responsibility for the process, function or quality system element audited.

Management responsible for the area audited implement timely corrective action to eliminate detected non-conformances and their causes, and initiate other appropriate action in response to opportunities for improvement identified by process participants or managers. Follow-ups are conducted to verify timely and effective implementation of the proposed action.

The Quality Manager or Operations Manager maintains all internal audit records, including internal auditor training records, results of internal audits and related follow-ups; periodically reviews internal audit results as well as progress towards achievement of company objectives aimed at improving overall QMS effectiveness and provides related recommendations for review by Top Management.

9.3 Management Review

9.3.1 General

Senior management shall review the QMS at least annually to evaluate its effectiveness. The management review evaluates the continuing suitability, adequacy and effectiveness of the QMS. The management review includes assessing opportunities for improvement and needed changes to the QMS. Records are maintained for each management review meeting on the Management Review Report.

9.3.2 Management Review Inputs include:

a) the status of actions from previous management reviews;
b) changes in the external and internal issues that are relevant to the Quality management system, such as;
    1. the needs and expectations of interested parties;
    2. risks and opportunities;
c) information on the performance and effectiveness of the Quality management system, including trends in:
    1) customer satisfaction and feedback from relevant interested parties;
    2) the extent to which Quality objectives have been met;
    3) process performance and conformity of products and services;
    4) nonconformities and corrective actions;
    5) monitoring and measurement results;
    6) audit results;
    7) the performance of external providers;
d) the adequacy of resources;
e) the effectiveness of actions taken to address risks and opportunities;
f) relevant communication(s) from interested parties, including complaints; and
g) opportunities for continued improvement.

9.3.3 Management Review Outputs include:

The outputs of the management review shall include decisions and actions related to:

a) Conclusions on the continuing suitability, adequacy and effectiveness of the QMS;
b) Decisions related to continual improvement opportunities;
c) Decisions related to any need for changes to the QMS, including resources;

d) Actions, if needed, when quality objectives have not been achieved;
e) Opportunities to improve integration of the QMS with other business processes, if needed; and
f) Any implications for the strategic direction of the organization.

Responsibilities for required actions are assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of management review.

10.0 Improvement

10.1 General

Access Assembly shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These shall include:

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

10.2 Nonconformity, Corrective Action and Preventive Action

10.2.1 Corrective action

The Top Management has overall responsibility for managing our corrective action process defined in *OP Section 29* and summarized below:

Evidence of nonconforming product, customer dissatisfaction, or ineffective processes is used to drive our corrective action system because a problem exists, requiring immediate correction and possible additional action aimed at eliminating or reducing the likelihood of its recurrence.

Management with responsibility and authority for corrective action are notified promptly of product or process non-conformities. Investigating and eliminating the root cause of these failures is a critical part of our continual improvement process.

Follow-ups are conducted (through the internal audit process to ensure that effective corrective action is taken appropriate to the impact of the problem encountered. In addition, the Quality Manager or Operations Manager summarizes and analyzes corrective action data to identify trends needed to assess overall effectiveness of the corrective action system and to develop related recommendations for improvement. The corrective action system is considered effective if specific problems are corrected and data indicates that the same or similar problems have not reoccurred. Results of this analysis and related recommendations are presented to Top Management for review and action during management reviews.

10.2.2 Preventive action

The Top Management has overall responsibility for managing our preventive action process defined in *OP Section 29* and summarized below:

Data from internal audits, customer feedback, employee suggestions, and other appropriate data is collected and analyzed to identify the actions needed to eliminate the causes of potential problems and thereby prevent their occurrence. Investigating and eliminating the root cause of potential failures is a critical part of our continual improvement process. We review and initiate preventive actions through our preventive action process defined in *OP Section 29*.

We apply controls and follow-up to ensure that effective preventive action is taken appropriate to the risk and impact of potential problems and losses. In addition, the Quality Manager or Operations Manager summarizes and analyzes preventive action data to identify trends needed to assess overall effectiveness of the preventive action system and to develop related recommendations for improvement. The preventive action system is considered effective if potential losses were avoided. Results of this analysis and related recommendations are presented to Top Management for review and action during management reviews.

10.3 Continual improvement

At Access Assembly LLC, the continual improvement process begins with the establishment of our quality policy and objectives for improvement, based on objectives contained in our Business Plan and customer targets/goals. Customer satisfaction, internal audit, process and product performance data, and the cost of poor quality are then compared to progress against objectives to identify additional opportunities for improvement. Appropriate improvement initiatives are established, supported and monitored for achievement through the use of our management review process. We also consider corrective and preventive actions a vital part of our continual improvement program. Corrective actions are initiated when desired results are not achieved and preventive actions are initiated to prevent the occurrence of problems or to implement other improvement actions. Besides the CAPA System, Management of Change forms (MOC), Form 090211 are used to document improvement, corrective and preventive actions; all management actions are prioritized and implemented on the basis of data analysis: the impact of failures/problems is used to prioritize needed corrective actions; risks are evaluated to identify and prioritize needed preventive actions; and cost/benefit analyses are performed to identify and prioritize needed improvement actions. Procedures governing our continual improvement system are detailed in *OP Section 29*.

The overall effectiveness of continual improvement program (including corrective and preventive actions taken as well as the overall progress towards achieving company objectives) is assessed through our management review process.

Essentially, such actions are effective if the problems corrected do not reoccur, potential problems identified do not occur, and other improvement actions accomplish the desired results or objectives. Inputs to the management review process are used to establish new/changed improvement objectives and to initiate/prioritize additional improvement actions.

> *The Top Management has overall responsibility for establishing and implementing an effective continual improvement system (OP Section 29) which includes improvement actions and corrective and preventive actions.*

11.0 Appendix A

List of Key Internal QMS Documents Referenced in this Manual

(A master lists for these and other QMS Documents are defined in OP Section 1A)

DOCUMENT TITLE	***DOCUMENT NO.***
QUALITY MANUAL	*QM01*
MASTER DOCUMENT LIST	*QM02*
QUALITY POLICY	*QMO3*
BUSINESS PLAN	*BP01*
MANAGEMENT AND ORGANIZATION	*OP SECTION 1B*
EQUIPMENT, CALIBRATION AND CONTROL	*OP SECTION 3C*
DEVICE HISTORY RECORD	*OP SECTION 5*
COMPONENTS, SPECIFICATION OF	*OP SECTION 7A*
PURCHASING & SUPPLIER CONTROLS	*OP SECTION 7B*
COMPONENTS, INCOMING INSPECTION OF	*OP SECTION 7C*
COMPONENTS, STOCKING AND ISSUING OF	*OP SECTION 7D*
COMPONENTS, TRACING OF	*OP SECTION 7F*
COMPONENTS, NUMBERING OF	*OP SECTION 7G*
CHANGE ORDERS	*OP SECTION 8*
DEVIATIONS, AUTHORIZED	*OP SECTION 9*
DOCUMENT CONTROL	*OP SECTION 10*
SAMPLES	*OP SECTION 11*
WORK IN PROCESS	*OP SECTION 12*
OPERATIONS STANDARD OPERATING PROCEDURE	*OP SECTION 12A*
FINAL INSPECTION	*OP SECTION 13*
COMPLAINT HANDLING	*OP SECTION 15A*
DEFECT TRACKING	*OP SECTION 16*
INTERNAL QUALITY AUDITS	*OP SECTION 18*
SERIAL NUMBER CONTROL	*OP SECTION 19*
ORDER PROCESSING	*OP SECTION 20*
BIDS AND CONTRACTS	*OP SECTION 21*
TRAINING	*OP SECTION 22*
QUALITY SYSTEM RECORD	*OP SECTION 23*
RECORDS MANAGEMENT AND ARCHIVING	*OP SECTION 23A*
SHIPPING	*OP SECTION 24*
INCOMING RECEIVING	*OP SECTION 25*
JOB SET-UP	*OP SECTION 26*
REWORK AND REPAIR	*OP SECTION 28*
CORRECTIVE AND PREVENTATIVE ACTION	*OP SECTION 29*
NON-CONFORMING MATERIAL	*OP SECTION 31*
STATISTICAL TECHNIQUES	*OP SECTION 32*
SPECIAL ORDER FORM	*FORM 090034*
PROCESS ASSESSMENT WORKSHEET	*FORM 090212*
MANAGEMENT OF CHANGE FORM	*FORM 090211*
CONTEXT OF THE ORGANIZATION WORKSHEET	*FORM 090213*
CONTINUAL IMPROVEMENT FORM	*FORM 090220*

0Appendix B

12.1Terms and Definitions

11.1.1 Acronyms

QMS	**Quality Management System**
OP	**Operating Procedure**
BP	**Business Plan**
COP	**Customer Oriented Process**
CIF	**Continual Improvement Form**
PAW	**Process Assessment Worksheet**

Terms and definitions contained in this manual and unique to our organization or business will be listed below. Customer definitions will take precedence over all other definitions.

Process Assessment: a technique employed at Access Assembly LLC to summarize key process inputs, outputs, control, measures of effectiveness/efficiency and other process data; resultant process assessment worksheets (PAW) are most often used by responsible managers (or internal auditors) to determine and document relevant process metrics as a basis for process development, monitoring and/or improvement. Another important and significant tool used to monitor/track objectives is the Continual Improvement Form (CIF) as well as using the Control Charts to monitor the progress of our production in different process areas.

Employee: Any person(s) whose day to day activities are directly supervised by authorized members of management at Access Assembly, and who is a full participant in the QMS, regardless of employment contract. Employees are to meet the same requirements, perform the same duties to the same expectations, regardless of employment contract holder.