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QUALITY MANAGEMENT SYSTEM

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QUALITY MANUAL

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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

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1. Scope

1.1 General

Access Assembly LLC, has based the Quality Management System (QMS) described in this manual to demonstrate our capability to consistently provide products/services that meet customer and applicable regulatory requirements, and to operate with increased effectiveness and efficiency with the overall aim of enhancing customer satisfaction.

Our QMS utilizes the process approach and quality management principles contained in the international standards: [ISO 9001:2000](#) to enhance our ability to continually improve.

1.2 Application

Our QMS complies with all applicable requirements contained in [ISO 9001:2000](#), covers the development and provision of all company products, and encompasses all operations at our facility located at 1208 Allanson Road, Mundelein, Illinois 60060. The following table identifies [ISO 9001:2000](#) requirements not applicable to our organization and provides a brief narrative justifying their exclusion from the scope of our QMS.

[ISO 9001:2000](#) Requirements EXCLUSION TABLE

Clause or Sub-clause	Exclusion	Justification
7.3	Design function from 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 performs all design development and provides all design specifications.
7.5	Only the Service portion from Production and Service Provision, not the entire 7.5 paragraph.	Service provision does not apply to Access Assembly LLC, as post product servicing is not within the scope of this company's services. The customer provides all design specifications and provides service provision for the completed product. Any Non-Conformity will be treated through the regular Non-Conformity Process

2. Reference Documents.

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

ISO 9001:2000, Quality management systems – Requirements

- [Customer Specific Requirements](#) (see Customer ref# QM02)
- [Customer Reference Manuals](#) (see Customer ref# 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.

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3. 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.

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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.

4.2 Documentation requirements

4.2.1 General

This manual contains documented statements of our quality policy and quality objectives and references documented procedures required by [ISO 9001:2000](#) 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. Refer to [OP Section 7A](#).
 - 2) Final test and inspection procedures for specific finished devices. Refer to [OP Section 13](#).
 - 3) Calibration procedures for specific pieces of test equipment. Refer to [OP Section 3C](#).
 - 4) Customer Requirements, Drawings of specific components. Refer to [OP Section 7A](#).

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 ([QMS Section 8.4](#)) 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 ([QMS Section 4.2.3](#)).

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4.2.2 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 9001:2000](#) requirements ([Section 1.2](#)) and defines the overall sequence of and interaction between our key QMS processes.

4.2.3 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](#).

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4.2.4 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.

5. Management Responsibility

5.1 Management commitment

Top Management provides evidence of its commitment to the development, implementation and improvement of our QMS as described in the following:

Our quality policy statement (*QMS Section 5.3*) documents and communicates the importance of meeting or exceeding all applicable requirements (including customer, 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 (*QMS Section 5.6*). 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 (*QMS Section 6.2.2*).

All managers demonstrate their commitment to the development and improvement of the QMS through the provision of necessary resources (*QMS Section 6.1*), through their involvement in the internal audit process (*QMS Section 8.2.2*), and through their proactive involvement in our continual improvement activities (*QMS Section 8.5.1*) – where emphasis is placed on improving both effectiveness and efficiency of our key QMS processes.

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5.2 Customer focus

Top management ensures a proper customer focus is established and maintained through the following activities:

Customer complaints and other customer input/feedback are continually monitored and measured to identify opportunities for improvement ([QMS Section 8.2.1](#)).

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 ([QMS Section 7.2](#)).

5.3 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. 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 ([QMS Section 5.4.1](#)).

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 ([QMS Section 6.2.2](#)).

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

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meetings ([QMS Section 5.6.2](#)).

5.4 Planning

5.4.1 Quality objectives

Our overall quality goal is to achieve our quality policy, and maintain the integrity of and continually improve a QMS compliant with [ISO 9001:2000](#). 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 [Continual Improvement Form, 8.5-6](#) and reviewed for achievement during management reviews ([QMS Section 5.6.2](#)). 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 Worksheets \(PAWs\), Form 8.4-1](#) and deployed to individuals or individual work areas and monitored for achievement through employee performance reviews ([QMS Section 6.2.2](#)).

Company and operational level improvement objectives are reviewed for consistency, accomplishment and clarity through our management review process ([QMS Section 5.6](#)) and may include any/all of the following possible measures:

- Customer Satisfaction: Operations Manager; [QMS Section 8.2.1](#).
- Supplier Performance: Operations Manager; [QMS Section 7.4.1](#).
- QMS Effectiveness: Operations Manager; [QMS Section 8.5.1](#).
- Overall Operational Efficiency and Manufacturing Process Efficiency: Operations Manager; [QMS Section 6.1](#)
- Training Effectiveness and Employee Awareness: Human Resources Functional Officer with input from the Operations Manager; [QMS Section 6.2.2](#).
- Effectiveness of Manufacturing Processes: Operations Manager; [QMS Section 7.5.1](#).
- Product Quality: Quality Manager and/or Operations Manager; [QMS Section 8.2.4](#).

Our top 5 objectives include the following performance criteria:

1. To reduce non-conformity to **0% defects** on products shipped to customer
2. To achieve **100% On-time delivery** performance.
3. To manage and control the facility, processes, quality systems and personnel to consistently and cost effectively produce products that meet customer needs and to **reduce waste to less than 2%**
4. To be committed to continuous process improvement, consistency and to **achieve 100% of Customer Requirements**.
5. To conduct our operations in conformance with, or to exceed, all applicable ISO 9001-2000 requirements).

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5.4.2 Quality management system planning

The Manager of QA or Operations Manager shall establish, implement, and maintain a quality plan that is appropriate to achieve the goals described in our Quality Policy ([QMS Section 5.3](#)). The specifics of the plan shall be included in the various sections of the *Procedure Manual*. The QMS planning process involves the establishment and communication of our quality policy ([QMS Section 5.3](#)) and objectives ([QMS Section 5.4.1](#)) through issuance of this manual and its associated procedures, and through the provision of resources needed for its effective implementation ([QMS Section 6.1](#)). Accordingly, this manual constitutes our overall plan for establishing, maintaining and improving an effective QMS. Our management review process ([QMS Section 5.6](#)) and internal audit process ([QMS Section 8.2.2](#)) ensure the integrity of our QMS is maintained when significant changes are planned and implemented that affect our key QMS processes.

The Quality Manager or the Operations Manager also develops appropriate quality planning documents for specific products, projects or contracts whenever customer requirements exceed the capability or intent of the product/service realization and support processes described in our QMS ([QMS Section 7.1](#)).

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

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 Section 5.3](#)), QMS Planning ([QMS Section 5.4.2](#)) including the establishment and deployment of objectives ([QMS Section 5.4.1](#)), the provision of resources needed to implement and improve the QMS ([QMS Section 6.1](#)) and management reviews ([QMS Section 5.6](#)). 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 ([QMS Section 5.4.1](#)), and the provision of resources needed to implement and improve these processes ([QMS Section 6.1](#)).

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Manager functions also conduct employee performance reviews ([QMS Section 6.2.2](#)). Management with responsibility and authority for corrective action are notified promptly of non-conformities ([QMS Section 8.5.2](#)). Management ensures that production is staffed with personnel in charge of, or delegated responsibility for product quality ([QMS Section 7.5.1](#)).

- Employees - All employees are responsible for the quality of their work and implementation of the policy and procedures applicable to processes they perform ([QMS Section 8.2.3](#)). Personnel responsible for product quality have the authority to stop production to correct quality problems ([QMS Section 8.3](#)). Employees are motivated and empowered ([QMS Section 6.2.2](#)) to identify and report any known or potential problems and recommend related solutions through internal audits ([QMS Section 8.2.2](#)) and/or the continual improvement and corrective/preventive action processes ([QMS Section 8.5](#)).

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.

5.5.2 Management representative

The Access Assembly LLC Operations Manager is appointed as Access Assembly LLC's management representative with delegated responsibilities for ensuring that an [ISO 9001:2000](#) compliant QMS is established, implemented, and maintained; for promoting awareness of customer requirements throughout the organization ([QMS Section 5.5.3](#)); and for ensuring that the performance of the QMS is reviewed by Top Management for effectiveness, continuing suitability and the need for improvement ([QMS Section 5.6](#)).

5.5.3 Internal communication

We communicate information regarding QMS processes and their effectiveness through documented training ([QMS Section 6.2.2](#)), the internal audit process ([QMS Section 8.2.2](#)), continual improvement and corrective/preventive action processes ([QMS Section 8.5](#)), 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 ([QMS Section 8.2.2](#)) 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.

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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 ([QMS Section 6.2.2](#)).

5.6 Management review

5.6.1 General

Top Management conducts a management review meeting at least once annually to ensure the continuing suitability, adequacy, and effectiveness of our QMS in accordance with procedures detailed in [OP Section 1B - Management and organization](#). The primary inputs reviewed include data that measures the conformance and performance of our QMS and recommendations based on analysis of such data. Conformance is primarily assured through internal audits ([QMS Section 8.2.2](#)) and demonstrated through a review of internal audit results and our demonstrated ability to correct/prevent problems. Performance is primarily assured through the deployment of company/operational objectives ([QMS Section 5.4.1](#)) and demonstrated through a review of our demonstrated ability to achieve desired results. The primary outputs of management review meetings are management actions taken ([QMS Section 8.5](#)) to make changes or improvements to our QMS and the provision of resources needed to implement these actions.

5.6.2 Review input

The management review meeting includes a review of our quality policy ([QMS Section 5.3](#)), all applicable requirements of the QMS, as well as review of

- a) results of audits as described in [OP Section 18](#),
- b) customer feedback,
- c) related performance trends and product conformity,
- d) status of preventive and corrective actions,
- e) follow-up actions from earlier management reviews,
- f) results of self assessments ([QMS Section 8.4](#)), and strategic or operational changes that could affect the QMS, and
- g) opportunities for improvement

This review shall also include:

- a) any corrective and/or preventive action instituted as a result of the audit, and whatever methods are appropriate to ascertain the effectiveness of that action
- b) review the Defect and Failure Analysis activities defined by [OP Section 16](#), at least once per quarter

At a minimum, company improvement objectives ([QMS Section 5.4.1](#)) documented in prior management reviews are reviewed for status and continuing suitability.

5.6.3 Review output

At a minimum, outputs from management review meetings include

- a) new/revised company improvement objectives and any related actions required for

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- improvement of the QMS and its processes,
- b) improvement of product related to customer requirements, and
- c) provision of resource needs.

Results of management review meetings are recorded and maintained as defined in [OP Section 1B - Management and organization](#).

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6. Resource Management

6.1 Provision of resources

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 Section 5.4.2](#), QMS Planning

[QMS Section 6.2.2](#), Human Resource Planning

[QMS Section 6.3](#), Plant, Facility, Equipment and other Infrastructure Planning

[QMS Section 6.4](#), Work Environment and Safety Planning

[QMS Section 7.1](#), Product Realization Planning

[QMS Section 7.2](#), Planning of Customer-related Processes

[QMS Section 7.4](#), Planning of Purchased Product (Materials, Services and Suppliers)

[QMS Section 7.5.1](#), Production Planning

[QMS Section 7.6](#), Measurement Systems Planning

[QMS Section 8.1](#), Measurement, Analysis and Improvement Planning

[QMS Section 8.5.1](#), 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 ([QMS Section 5.6](#)).

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.

6.2 Human resources

6.2.1 General

The employees are the most valuable resource and they are helped to achieve their full potential through continual education and training.

6.2.2 Competence, awareness 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.

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

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Top Management identifies emerging competency needs during management reviews ([QMS Section 5.6](#)). 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.

- b) *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.
- c) *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 ([QMS Section 5.6](#)).
- d) *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 ([QMS Section 5.3](#)) and objectives ([QMS Section 5.4.1](#)). This is accomplished through awareness training, employee performance reviews ([QMS Section 6.2.2](#)), and employee participation in our internal audit ([QMS Section 8.2.2](#)) and improvement ([QMS Section 8.5](#)) processes.
- e) *Records.* Appropriate records are maintained of education, training, skills and experience in accordance with provision of [QMS Section 4.2.4](#). 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.

6.3 Infrastructure

The Operations functional manager has overall responsibility for planning, providing and maintaining the resources needed to achieve product conformance, including buildings,

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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.

6.4 Work environment

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 audit ([QMS Section 8.2.2](#)) and improvement ([QMS Section 8.5](#)) activities. The HR functional manager has overall responsibility for identifying, implementing and maintaining effective employee benefit and workforce involvement programs.

The Safety functional 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.

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7. Product Realization

7.1 Planning of product realization

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, 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 ([QMS Section 8.2](#)), which may also include the use of appropriate statistical techniques ([QMS Section 8.1](#)).

7.2 Customer-related processes

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 and [QMS Section 8.2.1](#).

7.2.1 Determination of requirements related to the product

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 and 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.

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

7.2.2 Review of requirements related to the product

Contracting functional personnel or Operations Manager review customer requirements identified during the determination process ([QMS Section 7.2.1](#)) 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:

- a) 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.
- b) Contract or order requirements differing from those previously expressed are resolved
- c) Ensure Access Assembly LLC has the ability to meet the defined requirements.

Records of the review and actions resulting from the review are maintained ([QMS Section 4.2.4](#))

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](#).

7.2.3 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 on our assembling services as well as customized information for unique customer applications.

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- *Inquiries* are handled by our Operations Manager; [QMS Section 7.2.1](#). 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; see [QMS Section 8.2.1](#).

7.3 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.

7.4 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](#), [7E](#), and [7G](#) in accordance with the policies outlined in this section.

7.4.1 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 ([QMS Section 7.4.3](#) and [QMS Section 8.2.4](#)) to ensure conformity to specified purchase requirements ([QMS Section 7.4.2](#)).

[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.

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7.4.2 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.

7.4.3 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. Receiving inspection is performed per [QMS Section 8.2.4](#).

The Quality Manager plans and implements appropriate sampling plans and/or other statistical techniques to verify purchased product per [QMS Section 8.1](#).

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 per [QMS Section 7.4.2](#).

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.

7.5 Production and service provision

7.5.1 Control of production

We utilize a process-focused approach to plan and control operations and support services related to production. Service provision does not apply to Access Assembly LLC, as post product servicing is not within the scope of this company's services. 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.

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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; [QMS Section 6.3](#).
- 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; [QMS Section 7.6](#).
- 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* and [QMS Section 8.2.3](#). The Quality Manager or Operations Manager is responsible for planning and implementing in-process inspections needed to ensure process control and product quality; [QMS Section 8.2.4](#).
- 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; [QMS Section 7.5.3](#).

The Operations Manager periodically reviews operational data as well as progress towards achievement of company product performance objectives ([QMS Section 5.4.1](#)) and provides related recommendations for review by Top Management; [QMS Section 5.6.1](#).

7.5.2. Validation of processes for production

We define processes in which results cannot be verified by subsequent monitoring or measurement

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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.

7.5.3 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 requirements; [QMS Section 7.1](#). At a minimum, where products are made in lots or batches we identify and record a unique lot or batch number and related information; [QMS Section 7.5.1](#) and [OP Section 7F](#).

7.5.4 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](#).

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

7.5.5 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.
- While ACCESS ASSEMBLY LLC product is 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.

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

7.6 Control of monitoring and measuring devices

The Quality Manager or Operations Manger, is responsible for establishing and maintaining an effective system for identifying, selecting and controlling the use of monitoring and measuring devices 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 devices.

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 devices and verify their capability of meeting such requirements prior to use, when this equipment is not provided by the customer.

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Monitoring and measuring devices are used and controlled in a manner that ensures continuing suitability; 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 devices 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 devices that can affect product quality are 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. Access Assembly LLC does not have an internal laboratory facility and therefore cannot perform all required inspections, tests and/or calibrations; accordingly, external laboratories used for inspection, test or calibration services are selected, qualified and monitored per [QMS Section 7.4](#).
- b) When monitoring and measuring devices are 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; [QMS Section 8.5.2](#).
- c) Appropriate calibration records are maintained to document results of calibration activities ([QMS Section 4.2.4](#)) and suitable indicators are used to show current calibration status. A number or other identifier is used to provide traceability to the device calibration record
- d) All monitoring and measuring devices are safeguarded from adjustment that would invalidate the calibration.
- e) All monitoring and measuring devices are handled, maintained and stored in a manner that ensures accuracy and fitness for use is maintained.

8. Measurement, Analysis and Improvement

8.1 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, process monitoring and measurement, and product monitoring and measurement. [OP Section 32](#) details procedures governing the selection and use of appropriate statistical techniques used in monitoring, measurement, analysis and improvement activities.

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; [QMS Section 7.1](#). 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; see [QMS Section 6.2.2](#).

8.2 Monitoring and measurement

8.2.1 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 (see [QMS Section 7.2.1](#) and [QMS Section 7.2.2](#)) 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 ([QMS Section 7.2.3](#)) provide our primary basis for assessing customer satisfaction. Sales functional manager utilize a very simple customer satisfaction survey form to ascertain the customer’s overall perception of how well we are meeting their requirements and to document any recommendations for improvement.

Customer complaints (whether received in writing, verbally or electronically) are immediately forwarded to appropriate Sales functional manager for action. Customer complaints are documented and monitored through resolution through our continual improvement system; [QMS Section 8.5](#).

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; [QMS Section 8.5](#).

The Sales functional Manager or Operations Manger periodically reviews customer satisfaction

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survey data and other customer feedback (including complaints), as well as progress towards achievement of company customer satisfaction improvement objectives ([QMS Section 5.4.1](#)) and provides related recommendations for review by Top Management; [QMS Section 5.6](#).

8.2.2 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 9001:2000](#) 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.

Internal audits are conducted in accordance with a published schedule that identifies the audit scope and frequency. 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 ([QMS Section 6.2.2](#)) who preferably do not have direct responsibility for the activity 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 ([QMS Section 5.4.1](#)); and provides related recommendations for review by Top Management; [QMS Section 5.6](#).

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8.2.3 Monitoring and measurement of processes

We apply suitable methods for monitoring and measuring all QMS processes. QMS processes are documented measured, controlled and evaluated to ensure they are effective (i.e. achieve desired results) and to identify opportunities for improvement. At a minimum, managers with overall responsibility for carrying out a QMS process, analyzes process performance ([QMS Section 8.4](#)) and takes appropriate improvement, corrective or preventive action ([QMS Section 8.5](#)).

We conduct process oriented internal audits ([QMS Section 8.2.2](#)) 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.

8.2.4 Monitoring and measurement of product

The Quality Manager or Operations Manager has overall responsibility for planning ([QMS Section 7.1](#)) 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 (see [QMS Section 7.4.3](#)) 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. Test and inspection records are maintained for a minimum of three

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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 and tests have been completed, and records have been maintained providing evidence of conformity with acceptance criteria and identifying the person(s) authorizing release. 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](#).

8.3 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 ([QMS Section 7.5.3](#)) 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 ([QMS Section 8.5.2](#)) 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

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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; [QMS Section 7.5.3](#).

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.

8.4 Analysis of data

Top Management and other officers, managers and supervisors collect and analyze data using appropriate statistical techniques ([QMS Section 8.1](#)) 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 ([QMS Section 5.4.1](#)).

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 ([QMS Section 5.6.1](#)).

8.5 Improvement

8.5.1 Continual improvement

At Access Assembly LLC, the continual improvement process begins with the establishment of our quality policy ([QMS Section 5.3](#)) and objectives for improvement ([QMS Section 5.4.1](#)), 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; [QMS Section 8.4](#). Appropriate improvement initiatives are established, supported and monitored for achievement through the use of a Continual Improvement Form (CIF), [Form 8.5-6](#) and our management review process ([QMS Section 5.6](#)). 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 Action Requests (MARs), [Form 8.5-1](#) are used to document improvement, corrective and preventive actions; all management actions are prioritized and implemented on the basis of data analysis ([QMS Section 8.4](#)): 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

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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 ([QMS Section 5.6](#)).

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; [QMS Section 5.6](#).

The Top Management has overall responsibility for establishing and implementing an effective continual improvement system ([OP Section 29](#)) which includes improvement actions, as outlined in [QMS Section 8.5.1](#) above, and corrective and preventive actions as outlined in [QMS Section 8.5.2](#) and [QMS Section 8.5.3](#).

8.5.2 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; [QMS Section 8.2.2](#)) 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; [QMS Section 5.6](#).

8.5.3 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 ([QMS Section 8.4](#)) to identify the actions needed to eliminate the causes of potential problems and thereby prevent their occurrence. Investigating and eliminating

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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; [QMS Section 5.6](#).

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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](#))

Title	Document No.
Quality Manual	QM01
Customer Specific Requirements	QM02
Customer Manuals	QM03
Business Plan	BP01
COP Customer Oriented Process Model	COP-1
Master Documents List	OP Section 1A
Management and organization	OP Section 1B
Equipment, calibration & control	OP Section 3C
Device History Record	OP Section 5
Components, Specification	OP Section 7A
Purchasing & Supplier Controls	OP Section 7B
Components, Incoming Inspection of	OP Section 7C
Components, Stocking & Issuing of	OP Section 7D
Components, Tracing of	OP Section 7F
Components, Numbering of	OP Section 7G
Operations Document Control	OP Section 10
Samples	OP Section 11
Work in Process	OP Section 12
Standard Operating Procedure	OP Section 12A
Final Inspection	OP Section 13
Complaint Handling	OP Section 15A
Defect Tracking	OP Section 16
ESD Control	OP Section 17
Quality Audits	OP Section 18
Serial Number Control	OP Section 19
Order Processing Procedure	OP Section 20
Bids and Contracts	OP Section 21
Training Procedure	OP Section 22
Quality System Record	OP Section 23
Records Management and Archiving	OP Section 23A
Shipping Procedure	OP Section 24
Job Setup Verification	OP Section 26
CAPA	OP Section 29
Non-conforming Material	OP Section 31
Statistical Techniques	OP Section 32
Special Order Form	FORM 090034
Process Assessment Worksheet Form	PAW Form 8.4-1
Management Action Request	MAR Form 8.5-1
Continual Improvement Form	CIF Form 8.5-6

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Appendix B

Terms and Definitions

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:

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.

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