AS9100 & ISO 9001

QUALITY MANAGEMENT SYSTEM

MANUAL

The official controlled copy of this manual is the digitally signed PDF document on the Synergi Components, LLC network server and visible to all authorized users.

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QUALITY SYSTEMS MANUAL - TABLE OF CONTENTS

INTRODUCTION

Synergi Components, LLC. developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

To fully understand Synergi Components, LLC and its context, Synergi Components, LLC determined the external and internal issues that are relevant and that affect its ability to achieve the intended results of the quality management system.

The Quality Management System of Synergi Components, LLC meets the requirements of the international standard ISO 9001. The system addresses the design, development, production, installation, and servicing of the company's products. It incorporates the process approach where consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes.

This process approach provides for the management of the quality system and its processes through the application of a **"Plan-Do-Check-Act"** methodology and a focus on **"Risk-Based-Thinking"** leading to the prevention of undesirable outcomes.

The manual is divided into sections that correlate to the Quality Management System sections of ISO 9001:2015. The manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides the documented information with procedures or references for all activities comprising the Quality Management System that ensures the compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or interested parties. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

The manual is approved by a top management representative.

President : _____ Date 11/1/2019

1.0 – SCOPE

The scope of the Quality Management System is defined as everything within direct control and authority of Synergi Components, LLC The scope includes the organization's main processes for its product realization and service categories that include primary functions for "Distribution Management of Electronic Components".

Non-Applicability Synergi Components, LLC has determined that Section 8.3 Design is not applicable. The Organization maintains the design criteria/product requirements and the organization has not begun any design of service/logistics support to date. Justification: Synergi Components, LLC is a distributor of electronic components and does not design or develop products, customers specify all

principal product characteristics.

The Quality Management System will demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements and aims to enhance customer satisfaction through the effective application of the system.

1.1 Purpose of this Manual

Synergi Components, LLC's overall commitment to quality in work and customer service is defined through its Standardized Business Processes. Each of these processes align with the Quality Management System herein to create organized goals and a strategic organization. The Quality Management System as described herein this Quality Manual defines the corporation's commitment:

- By demonstrating its ability to consistently provide quality products and services that meet all customer satisfactory requirements.
- By addressing customer satisfaction through application of the system including processes and procedures for continual improvement of quality and prevention of non-conformities.
- Through employee empowerment, allowing the freedom for innovation and actions to improve performance.
- Through orderly change management that will maintain a high level of service and organization in the events of technological, technical skill or capability changes within Synergi Components, LLC

This Quality Systems Manual provides an overview of the quality processes, polices, and key requirements for the corporation. This Quality Systems Manual is the source of reference for all matters conferring and revolving around quality. It is available for inspection by our customers, potential customers, third party quality auditors and regulatory agencies.

2.0 – Normative References

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

2.1 Conformance and Compliance Standards

The Quality Systems Manual is intended to demonstrate conformance to

- SAE AS9100 *Quality Management Systems – Requirements for Aviation, Space and Defense Organizations.* This standard has been revised to incorporate the requirements of ISO 9001 as such, ISO 9001 has also been listed below as a standard to which this quality management system conforms.
- ANSI/ISO/ASQ Q9001 *American National Standard: Quality Management Systems – Requirements*. This standard is the United States' legal equivalent of the ISO 9001 international standard. These two standards may be referenced interchangeably in this manual and the quality management system. In all other references to this conformance standard in this manual or quality management system documents, the reference to the year of the current revision may or may not be used. Reference to this conformance standard also implies reference to all guidance standards contained therein.

3.0 – TERMS AND DEFINITIONS

3.1 Article: Material, part, component, assembly, or appliance which is listed by the design organization as eligible for installation in/on the product or included in the design data approved by the authority.

3.2 Authorized Release Certificate: Document attesting that a product is released for use (e.g., release or return to service) and certifying that the activities performed, and the results achieved, conform to established organization, regulatory, and customer requirements.

3.3 Certificate of Conformity (commonly referred to as a 'Certificate of Conformance'): Documented information that attests to product conformity; conformance to defined process, design, and specification requirements.

3.4 Counterfeit Part: An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer. NOTE: Examples of a counterfeit part can include, but are not limited to, the false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics.

3.5 Distributor: An organization carrying out the purchase, storage, splitting, or sale of products without affecting product conformity. The term 'organization' in the context of this standard means a distributor.

3.6 GFP/E: Government Furnished Property or Equipment

3.7 GFM: Government Furnished Material

3.8 Infrastructure: Buildings, workspace, utilities, process equipment and supporting services provided by Synergi Components, LLC determined as necessary to achieve conformity of product requirements.

3.9 ISO: International Organization for Standardization

3.10 Metrology: The science and practice of precision measurement, specifically the various disciplines of calibration required by Synergi Components, LLC

3.11 NCR: Non-Conformance Report – A system and specific document used to report and disposition non-conformances identified within our quality system.

3.12 PDF: Portable Document Format, a file system extension used to designate a document that conforms to the requirements of the international standard ISO 32000-1 *Document Management – Portable Document Format – Part 1: PDF 1.17*

3.13 Product Safety: Maintaining the state of product so that it is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

3.14 Product: The end result of meeting all contractual terms and conditions. Throughout this document and all documents related to the Quality Management System the word "service" is identical in meaning to "product."

3.15 Procedure: Maintained Documentation

3.16 QMS: Quality Management System

3.17 Record: Retained Documentation

3.18 Risk: An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

3.19 Splitting: The division of product either physically or by batch quantity, without affecting the product characteristics or conformity.

3.20 Special Requirements: Those requirements identified by the customer, or determined by the organization, which have high risks of not being met, thus requiring their inclusion in the operational risk management process. Factors used in the determination of special requirements include product or process complexity, past experience, and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

3.21 Suspected Unapproved Part: A part for which there is objective and credible evidence indicating that the part is likely an unapproved or counterfeit part. NOTE: This includes: articles shipped to an end user by a supplier who does not have direct delivery authorization from the approved production organization; new articles that do not conform to the approved design/data; articles that have not been manufactured or maintained by an approved source; articles that have been intentionally misrepresented, including counterfeit parts and articles with incomplete or inappropriate documentation.

3.22 Test Report: Documented information that shows objective evidence provided by either the manufacturer or a certified testing facility that the product conforms with specific design requirements, product or performance characteristics.

3.23 Unapproved Part: A part that was not produced or maintained in accordance with approved or acceptable data and applicable statutory, regulatory, and customer requirements.

3.24 USG: United States Government

3.25 SDS: Superior Development System

4.0 – Context of the Organization

4.1 Synergi Components, LLC and Its Context

Synergi Components, LLC has determined external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

Synergi Components, LLC will monitor and review the information about these external and internal issues.

This process is identified and defined in QOP-40-01 Organizational Context.

4.2 The Needs and Expectations of Interested Parties

Due to their effect or potential impact on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, Synergi Components, LLC has determined:

a) The interested parties that are relevant to the quality management system
b) The requirements of these interested parties that are relevant to the quality management system

Synergi Components, LLC has monitored and reviewed information about these interested parties and their relevant requirements.

This process is identified and defined in QOP-40-01 Organizational Context.

4.3 Determining the Scope of the Quality Management System

Synergi Components, LLC has determined the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, Synergi Components, LLC will consider:

a) The external and internal issues referred to in 4.1
b) The requirements of relevant interested parties referred to in 4.2
c) The products and services of the organization

Synergi Components, LLC will apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of the quality Management System: is "SYNERGi Components is a distributor of electronic components and Related equipment".

Synergi Components, LLC has determined that Section 8.3 Design is not applicable. The Organization maintains the design criteria/product requirements and the organization has not begun any design of service/logistics support to date. Justification: Synergi Components, LLC is a distributor of electronic components and does not design or develop products, Customer specify all principal product characteristics

Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

This process is identified and defined in QOP-40-01 Organizational Context.

4.4 Quality Management System and Its Processes

4.4.1 General

Synergi Components, LLC will establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

The organization's quality management system will also address customer and applicable statutory and regulatory quality management system requirements.

Synergi Components, LLC has determined the processes needed for the quality management system and their application throughout Synergi Components, LLC and shall:

a) Determine the inputs required and the outputs expected from these processes
b) Determine the sequence and interaction of these processes
c) Determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes

d) Determine the resources needed for these processes and ensure their availability
e) Assign the responsibilities and authorities for these processes
f) Address the risks and opportunities as determined in accordance with the requirements of 6.1
g) Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results
h) Improve the processes and the quality management system

NOTE: Sub clauses a) through h) are considered essential to the adoption of a process approach.

This requirement is addressed on FRM440-01 – QMS Process Matrix

4.4.2 REQUIREMENTS

To the extent necessary, Synergi Components, LLC shall:

a) Maintain documented information to support the operation of its processes
b) Retain documented information to have confidence that the processes are being carried out as planned

Synergi Components, LLC will establish and maintain documented information that includes:

a. A Quality Manual that contains information including documents, records and other related documented information established for the quality management system, or reference to it
b. a general description of relevant interested parties (see 4.2)
c. the scope of the quality management system, including boundaries and applicability (see 4.3)
d. a description of the processes needed for the quality management system and their application throughout the organization
e. the sequence and interaction of these processes
f. assignment of the responsibilities and authorities for these processes

This process is identified and defined in QOP-40-01 Organizational Context.

5.0 – LEADERSHIP

5.1 LEADERSHIP AND COMMITMENT

5.1.1 GENERAL

Top management will demonstrate leadership and commitment with respect to the quality management system by:

a) Taking accountability of 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 strategic direction and the context of the organization
c) Ensuring the integration of the quality management system 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 quality management system are available
f) Communicating the importance of effective quality management and of conforming to the quality management system requirements
g) Ensuring that the quality management system achieves its intended results
h) Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system
i) Promoting improvement
j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility

NOTE: Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence; whether Synergi Components, LLC is public, private, for profit or not for profit.

5.1.2 CUSTOMER FOCUS

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

a) Customer requirements and applicable statutory and regulatory requirements are determined, understood and consistently met
b) The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed
c) The focus on enhancing customer satisfaction is maintained
d) Product and service conformity and on-time delivery performance are measured and appropriate action is taken if intended results are not, or will not be, achieved

5.2 QUALITY POLICY

5.2.1 DEVELOPING THE QUALITY POLICY

Top management has established, implemented and maintained a quality policy that is identified in Appendix C Synergi Components, LLC that has ensured that this policy:

a) Is appropriate to the purpose and context of Synergi Components, LLC and supports its strategic direction
b) Provides a framework for setting quality objectives

c) Includes a commitment to satisfy applicable requirements
d) Includes a commitment to continual improvement of the quality management system

The quality policy and quality objectives are relevant to the company's goals and the expectations and needs of its customers. This policy has been communicated to all employees within the scope of the Quality Management System. Quality is paramount to the culture of Synergi Components, LLC

Top management ensures that its Quality Policy is understood through proper employee training and continuous communication.

5.2.2 COMMUNICATING THE QUALITY POLICY

The quality policy shall:

a) Be available and be maintained as documented information
b) Be communicated, understood and applied within the organization
c) Be available to relevant interested parties, as appropriate

5.3 ORGANIZATIONAL ROLES, RESPONSIBILITIES AND AUTHORITIES

5.3.1 MANAGEMENT REPRESENTATIVE

Top management will ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. Top management will assign the responsibility and authority for:

a) Ensuring that the quality management system conforms to the requirements of this International Standard
b) Ensuring that the processes are delivering their intended outputs;
c) Reporting on the performance of the quality management system and on opportunities for improvement to top management
d) Ensuring the promotion of customer focus throughout the organization;
e) Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented

Top Management has appointed the Quality Manager as Management Representative. As Management Representative the Quality Manager, in addition to the responsibilities associated with the Quality Manager, has the following authority:

- Ensure that processes and procedures needed for the Quality Management System are established, implemented and maintained
- Ensure that Quality Systems Manual requirements are established, implemented and maintained in accordance with the Standard
- Report on the performance of the Quality Management System and document needed improvements

- Act as a liaison with external parties, such as customers or auditors, on matters relating to the Quality Management System
- Organizational freedom and unrestricted access to top management to resolve matters pertaining to quality.
- Promote awareness of customer requirements throughout the organization

NOTE: The responsibility of a management representative includes being a liaison with external parties on matters relating to the quality management system.

6.0 – PLANNING

6.1 PLANNING

6.1 *ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES*

6.1.1 When planning for the quality management system, the organization will consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

6.1.1.1 give assurance that the quality management system can achieve its intended result(s)

6.1.1.2 enhance desirable effects

6.1.1.3 prevent, or reduce, undesired effects

6.1.1.4 Achieve improvement.

6.1.2 The organization will plan:

6.1.2.1 actions to address these risks and opportunities;

6.1.2.2 how to:

6.1.2.2.1 integrate and implement the actions into its quality management system processes (see 4.4);

6.1.2.2.2 Evaluate the effectiveness of these actions.

6.2 Actions taken to address risks and opportunities will be proportionate to the potential impact on the conformity of products and services.

NOTE 1: Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2: Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

This process is identified and defined in Procedure QP-60-01 Planning the Quality System and Risks

6.2 Quality Objectives and Planning to Achieve Them

Synergi Components, LLC will establish quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives shall:

a) Be consistent with the quality policy
b) Be measurable
c) Take into account applicable requirements
d) Be relevant to conformity of products and services and to enhancement of customer satisfaction
e) Be monitored
f) Be communicated
g) Be updated as appropriate

Synergi Components, LLC will retain documented information on the quality objectives.

6.3 Planning of Changes

Where Synergi Components, LLC determines the need for changes to the quality management system, the changes will be carried out in a planned and systematic manner. (see 4.4)

Synergi Components, LLC will consider:

a) the purpose of the changes and their potential consequences
b) the integrity of the quality management system
c) the availability of resource
d) The allocation or reallocation of responsibilities and authorities

7.0 Support

7.1 Resources

7.1.1 General

Top management of Synergi Components, LLC determines and provides, in a timely and effective manner, the resources needed:

- The implement, maintain, and improve the effective operations of the Quality Management Systems procedures, and
- To enhance customer satisfaction level by meeting and exceeding contractual requirements.

These resources are assessed and reviewed on a periodic basis consistent with annual and strategic business planning activities.

7.1.2 PEOPLE

Personnel assigned responsibilities directly or indirectly affecting the conformity to service requirements are determined to be qualified and competent based on education, training, observed skills and experience.

7.1.3 INFRASTRUCTURE

Synergi Components, LLC will determine, provide and maintain the infrastructure necessary for the operation of its processes to achieve conformity of products and services.

NOTE: Infrastructure can include:

- buildings and associated utilities
- equipment including hardware and software
- transportation resources
- Information and communication technology

7.1.4 ENVIRONMENT FOR THE OPERATION OF PROCESSES

Synergi Components, LLC will determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE: A suitable environment can be a combination of human and physical factors, such as:

- social (e.g. non-discriminatory, calm, non-confrontational)
- psychological (e.g. stress-reducing, burnout prevention, emotionally protective)
- physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise)

These factors can differ substantially depending on the products and services provided.

NOTE: Consideration of human factors is the understanding of the interactions between people, machines, and each other and their impact on human performance (e.g., physical fitness, physiological characteristics, personality, stress, fatigue, distraction, communication and attitude).

7.1.5 MONITORING AND MEASURING RESOURCES

7.1.5.1 GENERAL

Synergi Components, LLC will 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. Synergi Components, LLC will ensure that the resources provided:

a) are suitable for the specific type of monitoring and measurement activities being undertaken;
b) Are maintained to ensure their continuing fitness for their purpose.

Synergi Components, LLC will retain appropriate documented information as evidence of fitness for purpose of monitoring and measurement resources.

7.1.5.2 MEASUREMENT TRACEABILITY

Where measurement traceability is: a requirement or is considered by Synergi Components, LLC to be an essential part of providing confidence in the validity of measurement results, measuring equipment will be:

a) Verified or calibrated or both 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 calibration or verification will be retained as documented information
b) identified in order to determine their status
c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results

Synergi Components, LLC will establish, implement and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.

Synergi Components, LLC will maintain a register of the monitoring and measuring equipment. The register will include the equipment type, unique identification, location, and the verification or calibration method, frequency, and acceptance criteria. Verification or calibration will be carried out under suitable environmental conditions (see 7.1.4).

NOTE: Monitoring and measuring equipment can include, but are not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce verification data. It also includes personally owned and customer supplied equipment used to provide evidence of product and service conformity.

Synergi Components, LLC will 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 will take appropriate action as necessary

This process is identified and defined in Procedure QOP-715-01 Control of Monitoring and Measuring Resources

7.1.6 Organizational Knowledge

Synergi Components, LLC will determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge will be maintained, and made available to the extent necessary.

When addressing changing needs and trends, Synergi Components, LLC will consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

NOTE: 1: Organizational knowledge is knowledge specific to the organization; it is gained by experience. It is information that is used and shared to achieve the organization's objectives.

NOTE: 2: Organizational knowledge can be based on:

a) Internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services)
b) External sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers)

7.2 Competence

Synergi Components, LLC shall:

a) Determine the necessary competence of person(s) doing work under its control that affects performance and effectiveness of the quality management system
b) ensure that these persons are competent on the basis of appropriate education, training, or experience

c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken
d) Retain appropriate documented information as evidence of competence

NOTE: Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

NOTE: Consideration should be given for the periodic review of the necessary competency.

7.3 AWARENESS

Synergi Components, LLC will ensure that relevant persons doing work under the organization's control will be aware of:

a) the quality policy
b) relevant quality objectives
c) their contribution to the effectiveness of the quality management system, including the benefits of improved quality performance
d) The implications of not conforming with the quality management system requirements
e) Relevant quality management system documented information and changes thereto
f) Their contribution to compliance and product safety
g) The importance of ethical behavior

7.4 COMMUNICATION

Synergi Components, LLC will determine the internal and external communications relevant to the quality management system including:

a) On what it will communicate
b) When to communicate
c) With whom to communicate
d) How to communicate
e) Who communicates

NOTE: Communication should provide for internal and external feedback relevant to the quality management system.

This process is identified and defined in Procedure QOP-72-01 Competence, Awareness and Training.

7.5 DOCUMENTED INFORMATION

7.5.1 GENERAL

The organization's quality management system will include

a) documented information required by this International Standard
b) documented information determined by Synergi Components, LLC as being necessary for the effectiveness of the quality management system

NOTE: The extent of documented information for a quality management system can differ from one organization to another due to:

a) the size of organization and its type of activities, processes, products and services
b) the complexity of processes and their interactions
c) the competence of persons

7.5.2 CREATING AND UPDATING

When creating and updating documented information Synergi Components, LLC will ensure appropriate:

a) identification and description (e.g. a title, date, author, or reference number)
b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic)
c) Review and approval for suitability and adequacy.

NOTE: Communication should provide for internal and external feedback relevant to the quality management system.

7.5.3 CONTROL OF DOCUMENTED INFORMATION

7.5.3.1 PURPOSE

Documented information required by the quality management system and by this International Standard will be controlled to ensure:

a) It is available and suitable for use, where and when it is needed
b) It is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity)

7.5.3.2 REQUIREMENTS

For the control of documented information, Synergi Components, LLC will address the following activities, as applicable:

a) Distribution, access, retrieval and use

b) Storage and preservation, including preservation of legibility
c) Control of changes (e.g. version control)
d) Retention and disposition
e) Prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

Documented information of external origin determined by Synergi Components, LLC to be necessary for the planning and operation of the quality management system will be identified as appropriate, and controlled.

Documented information retained as evidence of conformity will be protected from unintended alterations.

When documented information is managed electronically, data protection processes shall be defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage).

Documented information that provides evidence of product origin, conformity, and shipment shall be retained.

NOTE: Examples of documented information that is retained may include, but is not limited to:

− Manufacturer, distributor, and repair station test and inspection reports;

− purchase orders/contracts;

− Certificates of conformity (manufacturer, sub-tier distributor), copies of authorized release certificates;

− Nonconformance, concession, and corrective actions;

− documented information of lot or batch traceability;

− documented information of storage, preservation, or shelf life condition (e.g., time, temperature, humidity).

NOTE: Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

This process is identified and defined in the following procedures:

Procedure QOP-75-01 Control of Documented Information

Procedure QOP-75-02 Control of Documents (Maintained Documents)

Procedure QOP-75-01 Control of Records (Retained Documents)

8.0 – OPERATION

8.1 OPERATIONAL PLANNING AND CONTROL

Synergi Components, LLC will plan, implement and control the processes, (see 4.4), needed to meet requirements for the provision of products and services and to implement the actions determined in Section 6, by:

a) Determining requirements for the product and services, such as
- personal and product safety
- Availability and inspect ability
- reliability, availability and maintainability
- product obsolescence
- prevention, detection, and removal of foreign objects
- handling, packaging and preservation
- recycling or final disposal of the product at the end of its life

b) Establishing criteria for
- the processes
- the acceptance of products and services

NOTE: According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support:

- process control
  - process capability measurements
  - statistical process control
  - design of experiment
- verification

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

d) Implementing control of the processes in accordance with the criteria

e) Determining and keeping documented information to the extent necessary
    1. To have confidence that the processes have been carried out as planned
    2. To demonstrate conformity of products and services to requirements
f) Engaging representatives of affected organization functions for operational planning and control
g) Determining the products and services to be obtained from external providers
h) Establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

NOTE: One method to achieve operational planning and control can be through using integrated phased processes.

As appropriate to the organization, customer requirements and products and services, Synergi Components, LLC will plan and manage product and service provision in a structured and controlled manner including timed events performed in the appropriate sequence to meet requirements at acceptable risk, with resource and schedule constraints. NOTE: This activity can be referred to as project management.

The output of this planning will be suitable for the organization's operations.

NOTE: documented information specifying the processes of the quality management system and the resources to be applied to a specific product, project or contract can be referred to as a quality plan.

Synergi Components, LLC will control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

Synergi Components, LLC will ensure that outsourced processes are controlled in accordance with section 8.4 Control of Externally Provided Products and Services.

Synergi Components, LLC will establish, implement and maintain a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements. The process will ensure that work transfer impacts and risks are managed.

NOTE: For the control of work transfer from Synergi Components, LLC to an external provider, or from an external provider to another external provider, see 8.4. For the control of work transfer from one organization facility to another, or from an external provider to the organization, see 8.5.

8.1.1 NOT USED

8.1.2 Configuration Management

Synergi Components, LLC will plan, implement and control a process for configuration management as appropriate to Synergi Components, LLC and product in order to ensure the visibility and control of physical and functional attributes throughout the product lifecycle. This process shall:

a) Control product identity and traceability to requirements, including the implementation of identified changes
b) Ensure that the documented information (e.g., requirements, design, test, and acceptance documentation) is accurate and consistent with the actual attributes of the products and services

This process is identified and defined in Procedure QOP-81-01- Configuration Management.

8.1.3 Not Used

8.1.4 Prevention of Counterfeit Product

Synergi Components, LLC will plan, implement and control a process, appropriate to the product, that prevents the use of counterfeit or suspect counterfeit product and their inclusion in product(s) delivered to the customer.

NOTE: Counterfeit product prevention processes should consider:

Training of appropriate persons in the awareness and prevention of counterfeit parts;

Application of a parts obsolescence monitoring program;

Controls for acquiring externally provided product from original or authorized manufacturers,

Authorized distributors, or other approved sources;

Requirements for assuring traceability of parts and components to their original or authorized manufacturers;

Verification and test methodologies to detect counterfeit parts;

Monitoring of counterfeit parts reporting from external sources;

Quarantine and reporting of suspect or detected counterfeit parts.

8.1.5 Prevention of Suspected Unapproved Parts

The organization shall plan, implement, and control a process appropriate to the organization and the product that identifies and prevents the release of unapproved and suspected unapproved parts.

NOTE: Suspected unapproved parts prevention processes should consider:

Training of appropriate persons in the awareness and identification of suspected unapproved parts;

Requirements for assuring traceability of parts and components to an authorized source;

Inspection processes to detect suspected unapproved parts;

Monitoring of suspected unapproved parts reporting from external sources;

Quarantine and reporting of suspected unapproved parts in accordance with applicable requirements from the competent authority or customers, as required.

This process is identified and defined in Procedure QOP-814-01 - Prevention of Counterfeit Product

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Communication with customers will include:

Providing information relating to products and services;

Handling enquiries, contracts or order handling, including changes;

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

handling or controlling customer property; if applicable;

Establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the Requirements Related to Products and Services

When determining the requirements for the products and services to be offered to customers, Synergi Components, LLC will ensure that:

the requirements for the products and services are defined, including:

any applicable statutory and regulatory requirements

those considered necessary by the organization

Synergi Components, LLC can meet the claims for the products and services it offers

8.2.3 Review of Requirements for Products and Services

8.2.3.1 General

Synergi Components, LLC will ensure that it has the ability to meet the requirements for products and services to be offered to customers. Synergi Components, LLC will conduct a review before committing to supply products and services to a customer, to include:

Requirements specified by the customer, including the requirements for delivery and post-delivery activities

Requirements not stated by the customer, but necessary for the specified or intended use, when known

Requirements specified by the organization

Statutory and regulatory requirements applicable to the products and services

Contract or order requirements differing from those previously expressed

This review will be coordinated with applicable functions of the organization.

If upon review Synergi Components, LLC determines that some customer requirements cannot be met or can only partially be met, Synergi Components, LLC will negotiate a mutually acceptable requirement with the customer.

Synergi Components, LLC will ensure that contract or order requirements differing from those previously defined are resolved.

The customer's requirements will be confirmed by Synergi Components, LLC before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.2 Documented Information

Synergi Components, LLC will retain documented information, as applicable:

a) On the results of the review
b) On any new requirements for the products and services

8.2.4 Changes to Requirements for Products and Services

Synergi Components, LLC will ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and Development of Products and Services Not Applicable

8.4 Control of Externally Provided Processes, Products, and Services

8.4.1 General

Synergi Components, LLC will ensure that externally provided processes, products, and services conform to requirements.

Synergi Components, LLC will be responsible for the conformity of all externally provided processes, products and services, including from sources defined by the customer.

Synergi Components, LLC will ensure, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.

Synergi Components, LLC will identify and manage the risks associated to the external provision of processes, products and services, as well as the selection and use of external providers (e.g., direct and sub-tier external providers and sources identified by the customer).

Synergi Components, LLC will require their external providers to apply appropriate controls to their sub-tier providers, to ensure that requirements are met.

Synergi Components, LLC will determine the controls to be applied externally provided processes, products and services when:

a. products and services from external providers are intended for incorporation into the organization's own products and services;
b. Products and services are provided directly to the customer(s) by external providers on behalf of the organization;
c. a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

Synergi Components, LLC will determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.

Synergi Components, LLC will retain documented information of these activities and any necessary actions arising from the evaluations.

NOTE: One factor that may be used during external provider selection and evaluation is quality data from objective and reliable external sources, as evaluated by Synergi Components, LLC (e.g., information from accredited quality management system or process certification bodies, organization approvals from government authorities). Use of such data would be only one element of an organization's external provider control process and Synergi Components, LLC remains responsible for verifying that externally provided processes, products and services meet specified requirements

8.4.1.1 Evaluating External Providers

Synergi Components, LLC shall:

a. Define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of external providers depending on their approval status
b. maintain a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family)
c. periodically review external provider performance including product and service conformity and on-time delivery performance

d. define the necessary actions to take when dealing with external providers that do not meet requirements
e. define the process for controlling documented information created by and/or retained by external providers

8.4.2 TYPE AND EXTENT OF CONTROL OF EXTERNAL PROVISION

Synergi Components, LLC will 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. Synergi Components, LLC shall:

a) ensure that externally provided processes remain within the control of its quality management system;
b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
c) Take into consideration:
    1. The potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements
    2. the effectiveness of the controls applied by the external provider
    3. the results of the periodic review of external provider performance (see 8.4.1.1 c)
d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements. (see 8.4.2.1)

8.4.2 VERIFICATION OF EXTERNAL PROVIDERS

Synergi Components, LLC will 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. Synergi Components, LLC shall:

a. Ensure that externally provided processes remain within the control of its quality management system;
b. Define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
c. Take into consideration:
    1. The potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements

2. The effectiveness of the controls applied by the external provider
3. The results of the periodic review of external provider performance (see 8.4.1.1 c)

d. Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements. (see 8.4.2.1)

8.4.2.1 VERIFICATION OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES

Verification activities of externally provided products and services will be performed according to the risks identified. These will include inspection or periodic testing, as applicable, when there is high risk of nonconformities or counterfeit product.

NOTE 1: Customer verification activities performed at any level of the supply chain does not absolve Synergi Components, LLC of its responsibility to provide acceptable products and services and to comply with all requirements.

NOTE 2: Verification activities can include:

a. review of objective evidence of the conformity of the processes, products and services from the external provider (e.g., accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter)
b. inspection and audit at the external provider's premises
c. review of the required documentation
d. review of production part approval process implementation
e. inspection of products or verification of services upon receipt

When external provider test reports are utilized to verify externally provided products, Synergi Components, LLC will have a process to evaluate the data in the test reports to confirm that the product meets requirements. When raw material is used in critical item applications, Synergi Components, LLC will have a process to validate the accuracy of test reports.

8.4.3 INFORMATION FOR EXTERNAL PROVIDERS

Synergi Components, LLC will ensure the adequacy of requirements prior to their communication to the external provider.

Synergi Components, LLC will communicate to external providers its requirements for the following:

a) The processes, products and services to be provided including the identification of specifications, drawings, process requirements, instructions and other relevant technical data
b) Approval of
    1. products and services
    2. methods, processes or 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 provider's performance to be applied by the organization
f) Verification or validation activities that the organization, or its customer, intends to perform at the external provider's premises
g) design and development control
h) critical items, including key characteristics
i) test, inspection and verification (including production process verification)
j) the use of statistical techniques for product acceptance and related instructions for acceptance by the organization
k) the need to:
    1. implement a quality management system
    2. use customer-designated or approved external providers, including process sources (e.g., special processes)
    3. notify Synergi Components, LLC of nonconforming processes, products or services and obtain approval for their disposition
    4. prevent the use of suspect unapproved, unapproved and counterfeit products (see 8.1.4)
    5. notify Synergi Components, LLC of changes to processes, products or services, including changes of external providers or location of manufacture, and obtain their approval
    6. flow down to their external providers applicable requirements including customer requirements
    7. provide a certificate of conformity, test reports, or authorized release certificate, as applicable
    8. retain documented information, including retention periods and disposition requirements
l) the right of access by the organization, their customer and regulatory authorities to the applicable areas of facilities and to applicable documented information
m) ensuring persons are aware of their contribution to compliance and product safety and of the importance of ethical behavior

This process is identified and defined in Procedures:

QOP-84-01 Purchasing

QOP-84-03 Verification of Purchased Products

8.5 PRODUCTION AND SERVICE PROVISION

8.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION

Synergi Components, LLC will implement production and service provision under controlled conditions. Controlled conditions will include, as applicable:

a) The availability of documented information that defines
    1. the characteristics of the products to be produced, the services to be provided, or the activities to be performed
    2. The results to be achieved

NOTE 1: Documented information that defines characteristics of products and services can include drawings, parts lists, materials and process specifications.

NOTE 2: Documented information for activities to be performed and results to be achieved can include process flow charts, control plans, production documents (e.g., manufacturing plans, travelers, routers, work orders, process cards) and verification documents.

b) The availability and use of suitable monitoring and measuring resources
c) The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs and acceptance criteria for products and services have been met
    1. Ensuring that documented information for monitoring and measurement activity for product acceptance includes:
        I. criteria for acceptance and rejection
        II. where in the sequence verification operations are to be performed
        III. measurement results to be retained (at a minimum an indication of acceptance or rejection)
        IV. any specific monitoring and measurement equipment required and instructions associated with their use
    2. Ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use
d) The use of suitable infrastructure and environment for the operation of processes; NOTE: Suitable equipment can include product specific tools (e.g., jigs, fixtures, molds) and software programs.
e) The appointment of competent persons, including any required qualification
f) The validation, and periodic revalidation, of the ability to achieve planned results of the process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement NOTE: These processes can be referred to as special processes (see 8.5.1.2)
g) The implementation of actions to prevent human error
h) the implementation of release, delivery, and post-delivery activities

i) The establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);
j) the accountability for all products (e.g., parts quantities, split orders, nonconforming product);
k) the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;
l) the provision for the prevention, detection, and removal of foreign objects;
m) the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (see 7.1.3);
n) the consequences of obsolescence (e.g., materials, components, equipment, products).

8.5.1.1 Control of Equipment, Tools, and Software Programs

Equipment, tools, and software programs used to automate, control, monitor, or measure processes shall be validated and maintained.

Storage requirements shall be defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

8.5.2 Identification and Traceability

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization shall maintain the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish controls for the media.

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

Unserviceable product shall be controlled and physically segregated from serviceable product.

NOTE: Traceability requirements can include:

1. the identification to be maintained throughout the product life;

2. the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap);
3. for an assembly, the ability to trace its components to the assembly and then to the next higher assembly;
4. the identification of the product's condition in inventory (e.g., new, overhauled, repaired, altered, rebuilt).

The organization shall maintain product identification and traceability by suitable means (e.g., labels, bar codes) from receipt; during splitting, storage, packaging, and preservation operations and until delivery. This includes handling or packing operations outsourced to external providers.

When delivering split product, the following information shall be retained:

1. amount delivered relative to amount received from external provider,
2. purchase order number(s),
3. Customer's name(s).

8.5.3 Property Belonging to Customers Or External Providers

Synergi Components, LLCwill exercise care with property belonging to the customer or external providers while it is under the organization's control or being used by the organization. Synergi Components, LLCwill identify, verify, protect and safeguard the customer's or external provider's property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, Synergi Components, LLCwill report this to the customer or external provider and retain documented information on what has occurred.

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

8.5.4 Preservation

Synergi Components, LLCwill preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

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

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

a) cleaning
b) prevention, detection and removal of foreign objects
c) special handling and storage for sensitive products
d) marking and labeling including safety warnings and cautions
e) shelf life control and stock rotation
f) special handling and storage for hazardous materials

8.5.5 Post-Delivery Activities

Synergi Components, LLCwill meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, Synergi Components, LLCwill consider:

a) Statutory and regulatory requirements
b) The potential undesired consequences associated with its products and services
c) The nature, use and intended lifetime of its products and services
d) Customer requirements
e) Customer feedback
f) product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).

   When problems are detected after delivery, the organization shall take appropriate action including investigation and reporting. NOTE: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.6 Control of Changes

Synergi Components, LLCwill review and control changes for production or service provision to the extent necessary to ensure continuing conformity with requirements.

Persons authorized to approve production or service provision changes will be identified.

Synergi Components, LLCwill retain documented information describing the results of the review of changes, the personnel authorizing the change, and any necessary actions arising from the review.

These Processes are identified and defined in procedure QOP-85-01 Control of Production and Service Provision

8.6 Release of Products and Services

Synergi Components, LLC will implement planned arrangements at appropriate stages to verify that product and service requirements have been met.

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

The release of products and services to the customer will not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

Synergi Components, LLC will retain documented information on the release of products and services. The documented information will include:

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

Synergi Components, LLC will ensure that all documented information required to accompany the products and services are present at delivery.

8.7 Control of Nonconforming Outputs

8.7.1 General

Synergi Components, LLC will ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

NOTE: The term “nonconforming outputs” includes suspected unapproved, unapproved, counterfeit, and nonconforming product or service generated internally, received from an external provider, or identified by a customer

Synergi Components, LLC will take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This will also apply to nonconforming products and services detected after delivery of the products or after the provision of the service.

The organization's nonconformance control process will be maintained as documented information including the provisions for:

Defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions

Taking actions necessary to contain the effect of the nonconformity on other processes, products or services

Timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties

Defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2)

NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors and regulatory authorities.

Synergi Components, LLC will deal with nonconforming outputs, in one or more of the following ways:

Correction

Segregation, containment, return or suspension of provision of products and services

Informing the customer

Obtaining authorization for acceptance under concession by a relevant authority and, when applicable, by the customer.

Dispositions of nonconforming product shall be limited to:

1. scrap;
2. Rejection for return to the external provider;
3. Rejection for revalidation by the manufacturer;

4. Submittal to either the customer or design authority for use-as-is disposition, as applicable.

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

Counterfeit, or suspect counterfeit, parts shall be controlled to prevent reentry into the supply chain.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 Documented Information Nonconforming Output

Synergi Components, LLC will retain documented information that

a) Describes the nonconformity
b) Describes the actions taken
c) Describes the concessions obtained
d) Identifies the authority deciding the action in respect of the nonconformity

These Processes are identified and defined in procedures
QOP-87-01 Control of Nonconforming Product

9.0 – Performance Evaluation

9.1 Monitoring, Measurement, Analysis, and Evaluation

9.1.1 General

Synergi Components, LLC will determine:

a) what needs to be monitored and measured
b) The methods for monitoring, measurement, analysis and evaluation, to ensure valid results
c) when the monitoring and measuring will be performed
d) When the results from monitoring and measurement will be analyzed and evaluated

Synergi Components, LLC will evaluate the quality performance and the effectiveness of the quality management system.

Synergi Components, LLC will retain appropriate documented information as evidence of the results.

9.1.2 CUSTOMER SATISFACTION

As one of the measurements of performance of the quality management system, Synergi Components, LLC monitors information relating to customer perception as to whether Synergi Components, LLC has fulfilled customer requirements. The method for obtaining and using this information is identified in procedure QOP-91-01 –Customer Satisfaction.

Information pertinent to evaluation of customer satisfaction includes, but not limited to, product conformity, on-time delivery performance, customer reviews, and corrective action requests. Synergi Components, LLC has developed and implemented plans for customer satisfaction improvements that address deficiencies identified by these evaluations; and, assesses the effectiveness of the results.

Note: Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, and dealer reports.

QOP-91-01 –Customer Satisfaction.

9.1.3 ANALYSIS AND EVALUATION

Synergi Components, LLC will analyze and evaluate appropriate data and information arising from monitoring, measurement

NOTE: Appropriate data can include information on product and service problems reported by external sources (e.g., government/industry alerts, advisories).

The results of analysis will be used to evaluate:

a) Conformity of products and services
b) The degree of customer satisfaction
c) The performance and effectiveness of the quality management system
d) If planning has been successfully implemented
e) The effectiveness of actions taken to address risks and opportunities
f) The performance of external provider(s)
g) The need for improvements to the quality management system

NOTE: Methods to analyze data can include statistical techniques.

9.2 INTERNAL AUDIT

9.2.1 GENERAL

Synergi Components, LLC will conduct internal audits at planned intervals to provide information on whether the quality management system:

a) Conforms to:
   1. The organization's own requirements for its quality management system
      NOTE: The organization's own requirements can include customer and applicable statutory and regulatory quality management system requirements
   2. The requirements of this International Standard
b) Is effectively implemented and maintained
   NOTE: When conducting internal audits, performance indicators can be evaluated to determine whether the quality management system is effectively implemented and maintained

9.2.2 REQUIREMENTS OF THE INTERNAL AUDIT

Synergi Components, LLC shall:

a) Plan, establish, implement and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which will take into consideration, the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
b) define the audit criteria and scope for each audit;
c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
d) ensure that the results of the audits are reported to relevant management;
e) Take appropriate corrective actions without undue delay
f) Retain documented information as evidence of the implementation of the audit program and the audit results.

These Processes are identified and defined in procedure QOP-92-01 Internal Audits

9.3 MANAGEMENT REVIEW

9.3.1 INPUTS OF THE MANAGEMENT REVIEW

Top management will review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

The management review will be planned and carried out taking into consideration:

a) The status of actions from previous management reviews;
b) Changes in external and internal issues that are relevant to the quality management system
c) Information on the performance and effectiveness of the quality management system, including trends in:
    - Customer satisfaction and feedback from relevant parties nonconformities and corrective actions
    - The extent to which quality objectives have been met
    - Process performance and conformity of products and services
    - Nonconformities and corrective actions
    - Monitoring and measurement results
    - Audit results
    - The performance of external providers;
    - On-time delivery performance
d) Adequacy of resources
e) The effectiveness of actions taken to address risks and opportunities (see clause 6.1)
f) Opportunities for improvement

9.3.2 Outputs of the Management Review

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

a) Opportunities for improvement
b) Any need for changes to the quality management system
c) Resource needs
d) Risks identified

Synergi Components, LLC will retain documented information as evidence of the results of management reviews.

This process is identified and defined in Procedure QOP-93-01 – Management Review.

10.0 – Performance Evaluation

10.1 General

Synergi Components, LLC will determine and select opportunities for improvement and implement necessary actions to meet customer requirements and enhance customer satisfaction. This will 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

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

10.2 NONCONFORMITY AND CORRECTIVE ACTION

10.2.1 ACTION TAKEN

When nonconformity occurs, including any arising from complaints, Synergi Components, LLC shall:

a) React to the nonconformity, and as applicable:
    1. Take action to control and correct it
    2. Deal with the consequences
b) Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
    1. Reviewing and analyzing the nonconformity
    2. Determining the causes of the nonconformity
    3. Determining if similar nonconformities exist, or could potentially occur
c) Implement any action needed
d) Review the effectiveness of any corrective action taken
e) Update risks and opportunities determined during planning, if necessary
f) Make changes to the quality management system, if necessary
g) flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity
h) take specific actions when timely and effective corrective actions are not achieved
i) Evaluate the need for action based on human factors to ensure nonconformities do not recur

Corrective actions will be appropriate to the effects of the nonconformities encountered.

10.2.2 DOCUMENTED INFORMATION OF NONCONFORMITIES

Synergi Components, LLC will retain documented information as evidence of:

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

These Processes are identified and defined in procedure QOP-1020-01 Nonconformity and Corrective Action.

10.3 CONTINUAL IMPROVEMENT

Synergi Components, LLC will continually improve the suitability, adequacy, and effectiveness of the quality management system.

Synergi Components, LLC will consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that will be addressed as part of continual improvement.

Synergi Components, LLC will monitor the implementation of improvement activities and evaluate the effectiveness of the results.

NOTE: Continual improvement opportunities can result from lessons learned, problem resolutions and the benchmarking of best practices

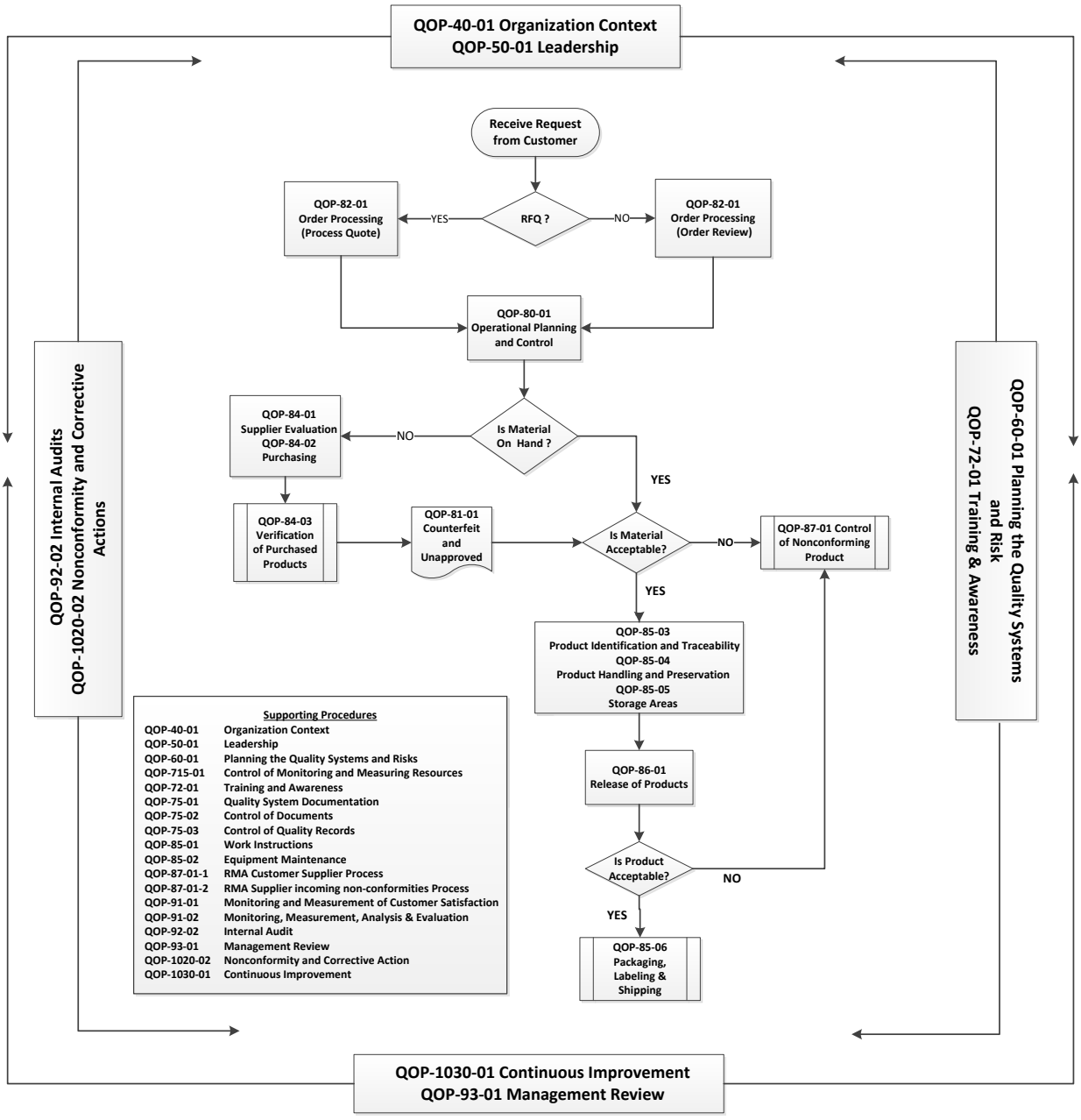
This process is identified and defined in Procedure QOP-1030-01 –Continuous Improvement.

REVISION HISTORY

Revision Level	Change Request Number	Date Approved	Authorized By
A	New	11/1/2019	H. Carter

APPENDIX A – SEQUENCE AND INTERACTION DIAGRAM

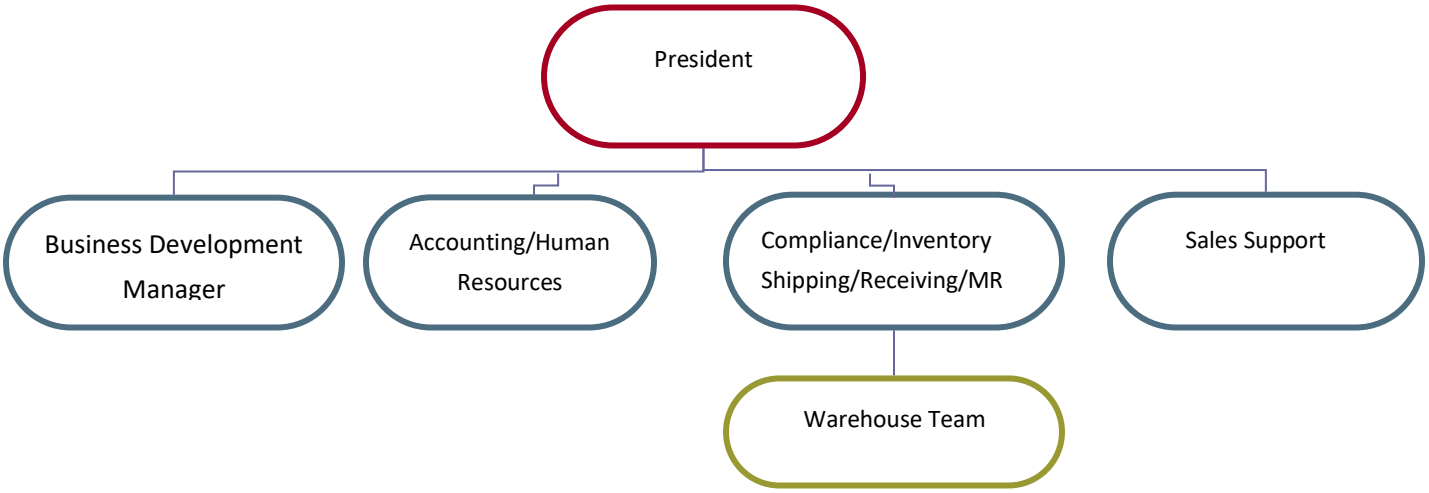
Appendix
Sequence and Interaction



Supporting Procedures

QOP-40-01	Organization Context
QOP-50-01	Leadership
QOP-60-01	Planning the Quality Systems and Risks
QOP-715-01	Control of Monitoring and Measuring Resources
QOP-72-01	Training and Awareness
QOP-75-01	Quality System Documentation
QOP-75-02	Control of Documents
QOP-75-03	Control of Quality Records
QOP-85-01	Work Instructions
QOP-85-02	Equipment Maintenance
QOP-87-01-1	RMA Customer Supplier Process
QOP-87-01-2	RMA Supplier incoming non-conformities Process
QOP-91-01	Monitoring and Measurement of Customer Satisfaction
QOP-91-02	Monitoring, Measurement, Analysis & Evaluation
QOP-92-02	Internal Audit
QOP-93-01	Management Review
QOP-1020-02	Nonconformity and Corrective Action
QOP-1030-01	Continuous Improvement

APPENDIX B – ORGANIZATION CHART



APPENDIX C – QUALITY POLICY

Synergi Components, LLC is a certified women owned business. We provide quality electronic components to customers worldwide. As an independent distributor, Synergi Components, LLC is committed to providing our customers new and original parts in a reasonable amount of time. We strive for continuous improvement and have established a Quality Management System which meets all requirements and provdes a framework for measuring and improving our performance.

Quality Objectives:

Synergi Components, LLC strives to maintain:

On-time delivery
Delivery of parts without any Quality issues (RMA's)