CARLIN SYSTEMS, INC.

QUALITY SYSTEM MANUAL

ISO 9001:2015
AS 9120B

REVISION J DATED 7/31/17

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CARLIN SYSTEM HISTORY AND SCOPE OF THE QMS

CARLIN SYSTEMS, INC.

Carlin Systems, Inc. (CSI) Originated in 1991 by John and Chris Giovan. Their goal was to provide superior service throughout the distribution cycle. As present, CSI occupies 8000 square feet of office and warehouse space in Bohemia, NY.

Carlin Systems services a wide variety of customers, both domestically and internationally, with electronic components as well as computer products. Some of our customers take advantage of our dock to stock program where our quality and reliability allow them to bypass their receiving inspection and enter the components directly into their inventory.

Carlin Systems' Quality Management System (QMS) covers the distribution of components and hardware for the Commercial, Military and Aerospace industries, and has been developed to meet the requirements of ISO 9001-2015 and AS 9120B Aerospace Quality Management Systems Requirements. The QMS excludes 8.3 Design and Development as Carlin Systems does not design or develop products.
Note that bold italic text indicates AS 9120 requirements.

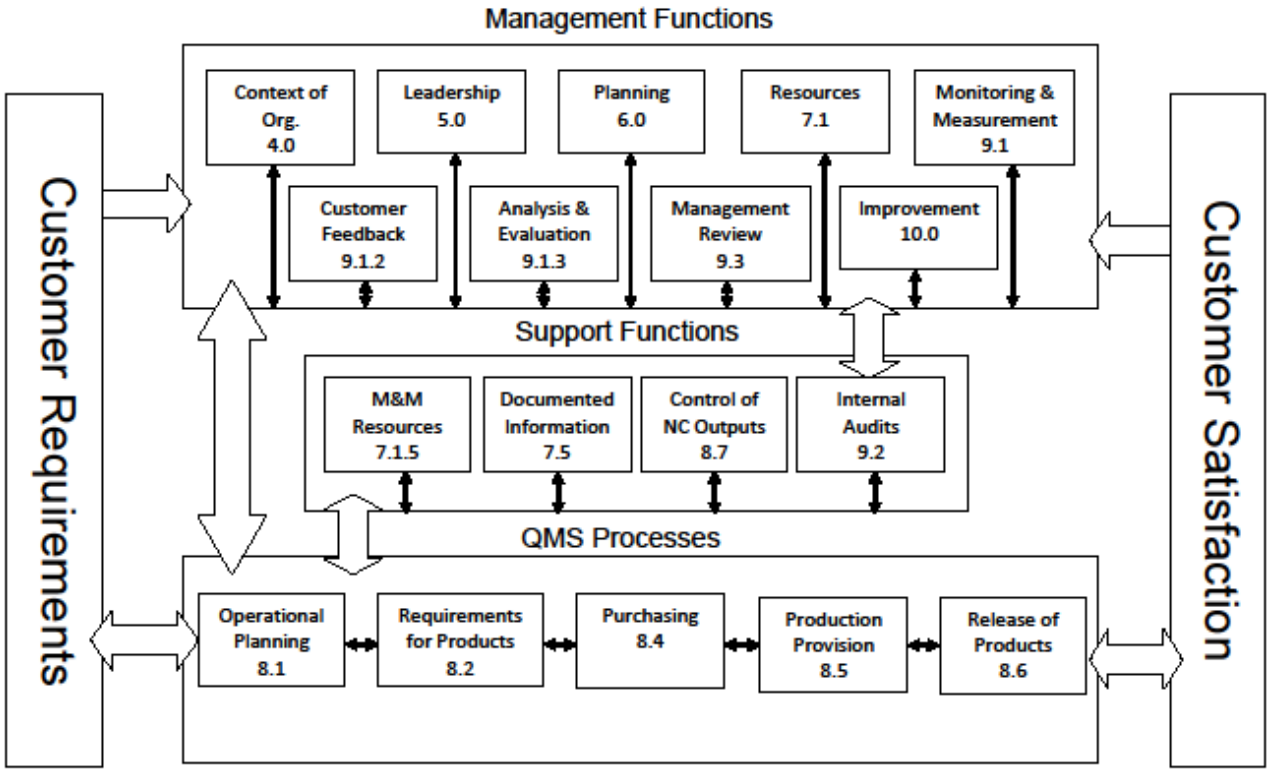
Carlin Systems is continually evaluating opportunities to obtain additional franchises as long as it enhances our service to present and future customers.

Carlin Systems is dedicated to providing our customers with superior service and quality products which are competitively priced and delivered on schedule.

John Giovan
President

Nicholas Giovan
AS/ISO Management Representative

INTERACTION OF QMS PROCESSES



CARLIN SYSTEMS, INC.
QUALITY POLICY

Carlin Systems is a customer oriented company that continually strives to meet or exceed our customer's requirements and expectations in quality, price, delivery and service innovation. In addition to these goals, Carlin Systems is committed to continually improving the effectiveness of our Quality Management System.

We provide our customers with quality products that are competitively priced and delivered on time.

QUALITY OBJECTIVES

Carlin Systems Quality Objectives for the coming year are to continue to improve our high level of:

- product conformity
- customer satisfaction
- on time delivery

John Giovan
President

CARLIN SYSTEMS, INC.

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SUMMARY OF CHANGES

Revision	Change(s)	Effective Date	Approved by
ORG	Original	August 1, 2003	
A	Added 7.5.1(f) and 7.5.4 to Quality Manual Scope (Section 4.2.2) as per audit	October 28, 2003	
B	Changed Quality Objective text to read "RMAs" not "customer returns" on page 4 of this manual; changed text of 8.2.4 and removed reference to "retired" SOP, as per audit	November 5, 2003	
C	Removed form 80203Rev. ORG on page 4	November 13, 2003	
D	Removed "at least" under 8.2.2 ;Added "Review of Manual" on page 9;Changed text under 7.2.3	November 4, 2004	
E	Added more objectives to be consistent with our quality policy on page 4	October 28, 2005	
F	Reviewed and adjusted the entire manual to comply with the latest ISO 9001-2008 standard.	May 18, 2010	
G	Revised page numbering	June 8, 2010	
H	Updated to AS9120A	May 15, 2014	
J	Updated to AS9120B	July 31, 2017	

REVIEW OF MANUAL

NAME	POSITION	SIGNATURE & DATE

4.0 Context of the Organization

4.1 Understanding the Organization and its Context

Executive Management determines 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.

Executive Management monitors and reviews information about these external and internal issues.

4.2 Understanding the Needs and Expectations of Interested Parties

Due to their effect or potential effect on Carlin Systems' ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, Executive Management determines:

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.

The organization monitors and reviews information about these interested parties and their relevant requirements.

Executive Management has identified internal interested parties as employees and process owners within the organization. External interested Parties include customers, suppliers, regulatory agencies (OSHA, EPA), and certification bodies. Executive Management monitors and reviews information and risk associated with these interested parties and their relevant requirements during the management review process (see 9.3).

4.3 Determinizing the Scope of the Quality Management System

Executive Management determines the boundaries and applicable of the quality management system to establish its scope.

When determining this scope, Executive Management considers:

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.

Executive Management applies all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of Carlin Systems' quality management system is available and maintained and retained as documented information. The scope states the types of products and services covered, and provide justification for any requirement of this International Standard that Executive Management determines is not applicable to the scope of its quality management system.

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

4.4 Quality Management System and its Processes

4.4.1 Executive Management establishes, implements, maintains and continually improves a quality management system, including the processes need and their interactions, in accordance with the requirements of this International Standard.

The Quality Management System addresses customer and applicable statutory and regulatory quality management system requirements.

Executive Management determines the processed needed for the quality management system and their application throughout the organization, and:

a) determines the inputs required and the outputs expected from these processes;

b) determines the sequence and interaction of these processes;

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

d) determines the resources needed for these processes and ensure their availability;

e) assigns the responsibility and authorities for these processes;

f) addresses the risks and opportunities as determined in accordance with the requirements of 6.1;

g) evaluates these processes, and implements any changes needed to ensure that these processes achieve their intended results;

h) improves the processes and the quality management system;

To the extent necessary, Executive Management:

a) maintains and retains documented information to support the operations of its processes;

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

Documented information has been established, maintained and retained, that includes:

- ***a general description of relevant interested parties;***

- ***the scope of the quality management system, including boundaries and applicability;***

- ***a description of the processes needed for the quality management system and their application throughout the organization;***

- ***the sequence and interaction of these processes;***

- ***assignment of the responsibilities and authorities for these processes.***

5.0 Leadership

5.1 Leadership and Commitment

5.1.1 General

Executive Management demonstrates leadership and commitment with respect to the quality management system by:

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

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

c) ensuring the integration of the quality management system requirements into the organization's business processes;

d) promoting the uses 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.

5.1.2 Customer Focus

Top Management demonstrates leadership and commitment with respect to customer focus by ensuring that:

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

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

c) the focus on enhancing customer satisfaction is maintained;

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

Leadership and commitment is addressed in SOP 5.6 Management Responsibility.

5.2 Policy

5.2.1 Establishing the Quality Policy

Executive Management establishes, implements and maintains a quality policy that:

a) is appropriate to the purpose and context of the organization 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.

5.2.2 Communicating the Quality Policy

The quality policy:

a) is available and is maintained and retained as documented information;

b) is communicated, understood and applied within the organization;

c) is available to relevant interested parties, as appropriate.

5.3 Organizational Roles, Responsibilities and Authorities

Executive Management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Executive Management assigns 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) ensuring that the processes of the quality management system and on opportunities for improvements (see 10.1), in particular to top management;

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

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

Executive Management has appointed a specific member of the organization's management, identified as the Management Representative, who has the responsibility and authority for oversight of the above requirements.

The Management Representative has the organizational freedom and unrestricted access to top management to resolve quality management issues.

Organizational Roles, Responsibilities and Authorities is address in SOP 5.6 Management Responsibility.

6 Planning

6.1 Actions to Address Risk and Opportunities

6.1.1 When planning for the quality management system, Executive Management considers the issues referred to in 4.1 and the requirements referred to in 4.2, and determines the risks and opportunities that need to be addressed to:

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

b) enhance desirable effects;

c) prevent, or reduce, undesired effects;

d) achieve improvement.

6.1.2 The organization plans:

a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement the actions into its quality management system processes (see4.4);

2) evaluate the effectiveness of these actions.

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

6.2 Quality Objectives and Planning to Achieve Them

6.2.1 Executive Management establishes quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives:

a) are consistent with the quality policy

b) are measurable;

c) take into account applicable requirements;

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

e) are monitored;

f) are communicated;

g) are updated as appropriate.

Executive Managements maintains and retains documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, Executive Management determines:

a) what is to be done;

b) what resources are required;

c) who is responsible;

d) when it is to be completed;

e) how the results are evaluated.

6.3 Planning of Changes

When Executive Management determines the need for changes to the quality management system, the changes are carried out in a planned manner (see4.4).

Executive Management considers:

a) the purpose of the changes and their potential consequences;

b) the integrity of the quality management system;

c) the availability of resources;

d) the allocation or reallocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

Executive Management determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

Executive Management considers:

a) the capabilities of, and constraints on, existing internal resources;

b) what needs to be obtained from external providers.

7.1.2 People

Executive Management determines and provides the person necessary for the effective implementation, maintenance and continual improvement of the quality management system.

Human Resources is addressed in SOP 6.2.2 Training.

7.1.3 Infrastructure

Executive Management determines, provides and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

7.1.4 Environment for the Operation Processes

Executive Management determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.

a) social (e.g. non-discriminatory, calm, non-confrontational);

b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);

c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

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

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

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

Executive Management ensures 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.

Executive Management retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement Traceability

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

a) calibrated or verified, 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 are 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.

Executive Management has established, implemented, and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification.

A register of the monitoring and measuring equipment is maintained and retained. The register includes the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.

Calibration or verification of monitoring and measuring equipment are carried out under suitable environmental conditions.

Executive Management determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and takes appropriate action as necessary.

7.1.6 Organizational Knowledge

Executive Management determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge is maintained and retained, and made available to the extent necessary.

When addressing changing needs and trends, Executive Management considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

Executive Management:

a) determines the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

b) ensures that these persons are competent on the basis of appropriate education, training, or experience;

c) where applicable, takes actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

d) retains appropriate documented information as evidence of competence.

7.3 Awareness

The organization ensures that persons doing work under the organization's control are 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 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 product or service conformity;

g) their contribution to product safety;

h) the importance of ethical behavior.

7.4 Communication

Executive Management determines the internal and external communication relevant to the quality management system, including:

a) on what it communicates;

b) when to communicate;

c) with whom to communicate;

d) how to communicate;

e) who communicates

7.5 Documented Information

7.5.1 General

The quality management system includes;

a) documented information required by the International Standard;

b) documented information determined by Executive Management as being necessary for the effectiveness of the quality management system.

7.5.2 Creating and Updating

When creating and updating documented information, Executive Management ensures 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.

7.5.3 Control of Documented Information

7.5.3.1 Documented information required by the quality management system and by the International Standard is 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 For the control of documented information, Executive Management addresses 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 reason.

Documented information of external origin determined by Executive Management to be necessary for the planning and operation of the quality management system are identified as appropriate, and be controlled.

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

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

Documented information is addressed in SOP 4.2.3 Document Control and SOP 4.2.4 Record Control.

8 Operation

8.1 Operational Planning and Control

Executive Management plans, implements and controls the processes (see 4.4) needed to meet the requirements for the provision of products and services, and implements the actions determined in Clause 6, by:

a) determining the requirements for the products and service;

b) establishing criteria for:

1) the processes;

2) the acceptance of products and services;

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

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

e) determining, maintaining and retaining documented information to the extent necessary;

1) to have confidence that the processes have been carried out as planned;

2) to demonstrate the conformity of products and services to their requirements.

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

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

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

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

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

As appropriate to the organization, customer requirements, and products and services, Executive Management plans and manages product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints.

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

Executive Management controls planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

Executive Management ensures that outsourced processes are controlled.

Executive Management establishes, implements, and maintains 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 ensures that work transfer impacts and risks are managed.

8.1.1 (Not Used)

8.1.2 Configuration Management

Executive Management plans, implements, and controls a process for configuration management as appropriate to the organization and its product and services in order to ensure

the identification and control of physical and functional attributes throughout the product lifecycle. This process:

a) ***controls product identity and traceability to requirements, including the implementation of identified changes;***

b) ***ensures that the documented information (e.g., requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services.***

8.1.3 (Not Used)

8.1.4 Prevention of Counterfeit Parts

Executive Management plans, implements, and controls processes, appropriate to the organization and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Communication with customer includes:

a) providing information relating to products and services;

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

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

d) handling or controlling customer property;

e) establishing specific requirements for contingency actions, when relevant

8.2.2 Determining the Requirements for Product and Services

When determining the requirements for the products and service to be offered to customers, Executive Management ensures that:

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

1) any applicable statutory and regulatory requirements;

2) those considered necessary by the organization;

b) Executive Management can meet the claims for the products and services it offers;

8.2.3 Review of the Requirements for Products and Services

8.2.3.1 Executive Management ensures that it has the ability to meet the requirements for products and services to be offered to customers. Executive Management conducts a review before committing to supply products and services to a customer to include:

a) requirements specified by the customer, but necessary for the specified or intended use, when know;

b) requirements not stated by the customer, but necessary for the specified or intended use, when know;

c) requirements specified by the organization;

d) statutory and regulatory requirements applicable to the products and services;

e) contract or order requirements differing from those previously expressed.

This review is coordinated with applicable functions of the organization.

If upon review Executive Management determines that some customer requirements cannot be met or can only partially be met, a mutually acceptable requirement is negotiated with the customer.

Executive Management ensures that contract or order requirements differing form those previously defined are resolved.

The customer's requirements are confirmed before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.2 Executive Management retains 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

Executive Management ensures 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.

Requirements for product and services are addressed in SOP 7.2 Contract Review.

8.3 (Not Used)

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General

Executive Management ensures that externally provided processes, products and services conform to requirements.

Carlin System is responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.

When required, it is ensured that customer-designated or approved external providers, including process sources (e.g., special processes), are used.

The risk associated with the external provision of processes, products, and services, as well as the selection and use of external providers are identified and managed.

If is required that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.

Executive Management determines the controls to be applied to 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.

Executive Management determines 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. The organization retains documented information of these activities and any necessary actions arising from the evaluation.

8.4.1.1 Executive Management:

a) defines the process, responsibilities, and authorities 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) maintains and retains 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 reviews external provider performance including process, product and service conformity, and on-time delivery performance;

d) defines the necessary actions to take when dealing with external providers that do not meet requirements;

e) defines the requirements for controlling documented information created by and/or retained by external providers.

8.4.2 Type and Extent of Control

Executive Management ensures that externally provides processes, products and services do not adversely affect the ability to consistently deliver conforming products and services to its customers.

Executive Management:

a) ensures that externally provided processes remain within the control of its quality management system;

b) defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

c) taken into consideration:

1) the potential impact of the externally provided processes, products and services on the ability to consistently meet customer 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;

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

Verification activities of externally provided processes, products, and services are performed according to the risks identified by Executive Management. These include inspection or periodic testing, as applicable, when there is a high risk of nonconformities including counterfeit parts.

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

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

When verification activities are delegated to the external provider, the scope and requirements for delegation are defined and a register of delegations is maintained and retained. The external provider's delegation verification activities are periodically monitored.

When external provider test reports are utilized to verify externally provided products, a process to evaluate the data in the test reports is implemented to confirm that the product meets requirements. When a customer or organization has identified raw material as a significant risk, a process to validate the accuracy of test report is implemented.

8.4.3 Information for External Providers

Executive Management ensures that adequacy of requirements prior to their communication to be external provider.

Executive Management communicates to external providers its requirement for:

a) the processes, products and services to be provided ***including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instruction;***

b) the approval of:

1) products and services;

2) methods, processes and equipment;

3) the release of products and services;

c) competence, including any required qualification of persons;

d) the external providers' interaction with Carlin Systems;

e) control and monitoring of the external provider's performance to be applied by the organization;

f) verification or validation activities that Carlin Systems, or its customer, intends to perform at the external providers' premises;

g) test, inspection, and verification;

h) the use of statistical techniques for product acceptance and related instructions for acceptance by the organization;

i) the need to:

- ***implement a quality management system;***

- ***use customer-designated or approved external providers, including process sources (e.g., special processes;***

- ***notify of nonconforming processes, product, or services and obtain approval for their disposition;***

- ***prevent the use of suspected unapproved, unapproved, counterfeit parts (see 8.1.4 and 8.1.5);***

- ***notify of change to processes, products, or services, including changes of their external providers or location of manufacturer, and obtain the organization's approval;***

- ***flow down to external providers applicable requirements including customer requirements;***

- ***a certificate of conformity, test reports, of authorized release certificate, as applicable;***

- ***retain documented information, including retention periods and disposition requirements;***

j) the right of access by Carlin Systems, our customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;

k) ensuring that persons are aware of:

- ***their contribution to product or service conformity;***

- ***their contribution to product safety;***

- ***the importance of ethical behavior.***

Control of Externally Provided Processes, Products and Services is addressed in SOP 7.4 Purchasing.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

Executive Management implements production and service provision under controlled conditions. Controlled conditions 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;

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 measuring activity for product acceptance includes:

- ***criteria for acceptance and rejections;***

- ***where in the sequence verification operations are to be performed;***

- ***measurement results to be retained (at a minimum an indication of acceptance or rejection);***

- ***any specified monitoring and measuring 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;

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

f) the validation, and periodic revalidation, of the ability to achieve planned results of processed for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

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 obsolesces (e.g., materials, components, equipment, products).

8.5.1.1 Control of Equipment, Tools, and Software Programs

Equipment, tools, and software program used to automate, control, monitor, or measure production processes are validated prior to final release for production and are maintained.

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

8.5.2 Identification and Traceability

Suitable means to identify outputs is used when it is necessary to ensure the conformity of products and services.

The identification of the configuration of the products and services is maintained in order to identify any differences between the actual configuration and the required configuration.

Status of outputs are identified with respect to monitoring and measurement requirements throughout production and service provision.

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

The unique identification of the outputs is controlled when traceability is a requirement, and retains the documented information necessary to enable traceability.

Unserviceable product is controlled and physically segregated from serviceable product.

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

When delivering split product, the following information is retained:

- amount delivered to amount received from external provider,

- purchase order number(s)

- Customer's name(s)

8.5.3 Property Belonging to Customers or External Providers

Care is exercised with property belonging to customers or external providers while it is under Carlin System's control or being used by Carlin System.

Customers' or external providers' property provided for use or incorporation into the products and services is identified, verified, protected and safeguarded.

When the property of a customer or external provider is lost, damaged or otherwise found to be suitable for use. Executive Management reports this to the customer or external provider and retain documented information on what has occurred.

8.5.4 Preservation

Executive Management preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

Preservation of outputs also includes, 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 warning and cautions;

e) shelf life control and stock rotations;

f) special handling and storage for hazardous materials.

8.5.5 Post-Delivery Activities

Executive Management meets requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required.

Executive Management considers:

a) statutory and regulatory requirements;

b) the potential undesired consequences associated with its product 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, appropriate action is taken including investigation and reporting.

8.5.6 Control of Changes

Executive Management reviews and controls 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 are identified.

Executive Management retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

Product and service provision is addressed in SOP 7.5 Process Control.

8.6 Release of Products and Services

Executive Management implements planned arrangement, at appropriate stages, to verify that the product and service requirements have been met.

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

Executive Management retains documented information on the release of products and services. The documented information includes:

a) evidence of conformity with the acceptance criteria;

b) traceability to the person(s) authorizing the release.

It is ensured that all documented information required to accompany the products and services are present at delivery.

8.7 Control of Nonconforming Outputs

8.7.1 Executive Management ensures that outputs that to not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

Executive Management takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, during or after the provision of services.

The nonconformity control process is maintained and retained 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).***

Executive Management deals with nonconforming outputs in one or more of the following ways:

a) correction;

b) segregation, containment, return or suspension of provision of products and services;

c) informing the customer;

d) obtaining authorization for acceptance under concession.

Disposition of nonconforming products is limited to:

- ***scrap;***

- ***rejection for return to the external provider;***

- ***rejection for revalidation by the manufacturer;***

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

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

Counterfeit, or suspect counterfeit, parts are controlled to prevent re-entry into the supply chain.

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

8.7.2 Executive Management retains documented information that:

a) describes the nonconformity;

b) describes the action taken;

c) describes any concessions obtained;

d) identified the authority deciding the action in respect of the nonconformity.

Control of nonconforming outputs is addressed in SOP 8.3 Nonconforming Material.

9 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

Executive Management determines;

a) what needs to be monitored and measured;

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

c) when the monitoring and measuring is to be performed;

d) when the results from monitoring and measurement are analyzed and evaluated.

Executive Management evaluates the performance and the effectiveness of the quality management system. Executive Management determines the methods for obtaining, monitoring and reviewing this information.

Information to be monitored and used for the evaluation of customer satisfaction includes, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. Plans are developed and implemented for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

9.1.3 Analysis and Evaluation

Executive Management analyzes and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis are 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 implemented effectively;

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

f) the performance of external providers;

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

9.2 Internal Audits

9.2.1 Executive Management conducts internal audits at planned intervals to provide information on whether the quality management system:

a) conforms to:

1) Carlin Systems' own requirements for its quality management system;

2) the requirements of the International Standard.

b) is effectively implemented and maintained.

9.2.2 Executive Management

a) plans, established, implements and maintains an audit program(s) including the frequency, methods, responsibilities, planning requirement and reporting, which takes into consideration the importance of the processes concerned, changes affecting Carlin Systems, and the results of previous audits.

b) defines the audit criteria and scope for each audit;

c) selects auditors and conducts audits to ensure objectivity and the impartiality of the audit process;

d) ensures that the results of the audits are reported to relevant management;

e) takes appropriate correction and corrective actions without undue delay;

f) retains documented information as evidence of the implementation of the audit program and the audit results,

Internal audits are addressed in SOP 8.2.2 Internal Audits.

9.3 Management Review

9.3.1 General

Executive Management reviews the quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction.

9.3.2 Management Review Inputs

The management review is 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:

1) customer satisfaction and feedback from relevant interested parties;

2) the extent to which quality objectives have been met;

3) process performance and conformity of products and services;

4) nonconformities and corrective actions;

5) monitoring and measurement results;

6) audit results;

7) the performance of external providers;

8) on-time delivery performance;

d) the adequacy of resources;

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

f) opportunities for improvement.

9.3.3 Management Review Outputs

The outputs of the management review 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

Executive Management retains documented information as evidence of the results of management reviews.

Management review is addressed in SOP 5.6 Management Responsibility.

10 Improvement

10.1 General

Executive Management determines and selects opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These include:

a) improving products and services to meet requirements as well as to address future needs and expectations;

b) correction, preventing or reducing undesired effects;

c) improving the performance and effectiveness of the quality management system.

10.0 Nonconforming and Corrective Action

10.2.1 When a nonconforming occurs, including any arising from complaints, Executive Management:

a) reacts to the nonconformity and, as applicable:

1) takes action to control and correct it;

2) deals with the consequences;

b) evaluates 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 ***including, as applicable, those related to human factors;***

3) determining is similar nonconformities exist, or could potentially occur;

c) implements any action needed;

d) reviews the effectiveness of any corrective action taken;

e) updates risks and opportunities determined during planning, if necessary;

f) makes changes to the quality management system, if necessary;

g) flows down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;

h) takes specific actions when timely and effective corrective actions are not achieved.

Corrective actions are appropriate to the effects of the nonconformities encountered.

Documented information is maintained and retained that defines the nonconformity and corrective action management processes.

10.2.2 Executive Management retains documented information as evidence of:

a) the nature of the nonconformities and any subsequent action taken;

b) the results of any corrective action.

Corrective action is addressed in SOP 8.5.2 Corrective Action.

10.3 Continual Improvement

Executive Management continually improves the suitability, adequacy and effectiveness of the quality management system.

Executive Management considers the results of analysis and evaluation, and the outputs form management review, to determine if there are needs or opportunities that are addressed as a part of continual improvement,

Implementation of improvement activities are monitored and the effectiveness of the results are evaluated.

Improvement is addressed in SOP 8.5.3 Preventive Action.

ISO 9100D Clause Number	Equivalent QMS Document Reference
4 Quality Management System	
4.1 Understanding the organization and its context	Quality System Manual
4.2 Understanding the needs and expectations of interested parties	Quality System Manual
4.3 Determining the scope of the quality management system	Quality System Manual
4.4 Quality management system and its processes	Quality System Manual
5 Leadership	
5.1 Leadership and commitment	SOP 5.6
5.2 Policy	SOP 5.6
5.3 Organizational roles, responsibilities and authorities	SOP 5.6
6 Planning	
6.1 Actions to address risks and opportunities	Quality System Manual
6.2 Quality objectives and planning to achieve	Quality System Manual
6.3 Planning of changes	Quality System Manual
7 Support	
7.1 Resources	SOP 6.2
7.1.1 General	SOP 6.2
7.1.2 People	SOP 6.2
7.1.3 Infrastructure	SOP 7.5
7.1.4 Environment for the operation of processes	SOP 7.5
7.1.5 Monitoring and measuring resources	Quality System Manual
7.1.6 Organizational knowledge	Quality System Manual
7.2 Competence	SOP 6.2
7.3 Awareness	Quality System Manual
7.4 Communication	Quality System Manual
7.5 Documented Information	SOP 4.2.3
7.5.1 General	SOP 4.2.3
7.5.2 Creating and Updating	SOP 4.2.3
7.5.3 Control of Documented Information	SOP 4.2.4
8 Operation	

8.1 Operational planning and control	Quality System Manual
8.2 Requirements for products and services	SOP 7.2
8.2.1 Customer communication	SOP 7.2
8.2.2 Determination of requirements related to products and services	SOP 7.2
8.2.3 Review of requirements related to products and services	SOP 7.2
8.2.4 Changes to requirements for products and services	SOP 7.2
8.3 Design and development of products and services	n/a
8.3.1 General	n/a
8.3.2 Design and development planning	n/a
8.3.3 Design and development inputs	n/a
8.3.4 Design and development controls	n/a
8.3.5 Design and development outputs	n/a
8.3.6 Design and development changes	n/a
8.4 Control of externally provided processes, products and services	SOP 7.4
8.4.1 General	SOP 7.4
8.4.2 Type and extent of control	SOP 7.4
8.4.3 Information for external providers	SOP 7.4
8.5 Production and service provision	SOP 7.5
8.5.1 Control of production and service provision	SOP 7.5
8.5.2 Identification and traceability	SOP 7.5
8.5.3 Property belonging to customers or external providers	SOP 7.5
8.5.4 Preservation	SOP 7.5
8.5.5 Post-delivery activities	n/a
8.5.6 Control of changes	SOP 7.5
8.6 Release of products and services	SOP 7.5
8.7 Control of nonconforming outputs	SOP 8.3
9 Performance evaluation	
9.1 Monitoring, measurement, analysis and evaluation	SOP 5.6
9.1.1 General	SOP 5.6

9.1.2 Customer satisfaction	SOP 5.6
9.1.3 Analysis and evaluation	SOP 5.6
9.2 Internal audit	SOP 8.2.2
9.3 Management review	SOP 5.6
10 Improvement	
10.1 General	Quality System Manual
10.2 Nonconformity and Corrective Action	SOP 8.5.2
10.3 Continual Improvement	SOP 8.5.3