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Quality Manager	0001

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REVISION HISTORY

SEC	REV	CHANGE	DATE	AUTHORITY
ALL	A	NEW	11/19/03	Thomas Murphy
ALL	B	General Review + Update	5/4/05	Thomas Murphy
ALL	C	General Review + Update	5/1/08	Thomas Murphy
ALL	D	Review SNL, NQA, and HS audits	6/9/09	Thomas Murphy
ALL	E	Review and revised to AS9100C	3/23/10	Thomas Murphy
ALL	F	Added 7.1.1, .2, +.3, Project, Risk, and Config. Mang.	9/27/10	Thomas Murphy
ALL	G	Removed "service" from 7.5.1 added 7.5.1.3	10/25/10	Thomas Murphy
ALL	H	Removed "sold at competitive prices" from Quality Policy.	7/26/11	Thomas Murphy
ALL	J	General Review and update. Add VP title and revise authority	9/12/13	Thomas Murphy
ALL	K	Revise 5.4.1 remove “competitive prices”	7/11/16	Thomas Murphy
ALL	L	Review and Revised to AS9100D	8/8/17	Thomas Murphy
ALL	M	Revised Process Interaction Matrix per 2019 NQA Audit.	8/9/19	Thomas Murphy
ALL	N	Revised per restructuring	5/26/20	Thomas Murphy
ALL	O	Revised per restructuring	4/12/21	Thomas Murphy

1.0 SCOPE

INTRODUCTION

EVANS CAPACITOR COMPANY has developed this quality management system to satisfy the needs of its customers and to improve management of the company. The quality system complies with the international standard AS9100D for the design, manufacture, and distribution of capacitors and capacitor modules for use in military, aerospace, commercial, and industrial applications. If there is a conflict between the requirements in this standard and customer or applicable statutory or regulatory requirements, the latter shall take precedence.

The *EVANS CAPACITOR COMPANY* is headquartered in East Providence, RI with an additional manufacturing-only facility located in Sanford, ME.

The manual is divided into sections corresponding to quality system requirements of the AS9100D standard. Each section starts with a statement expressing the general principles and commitment to implement specific actions pertaining to the quality system element that is the subject of the section. The statement is followed by a general and brief procedure outlining how these activities are carried out and referencing the operating procedures that provide more detailed descriptions.

The purpose of this manual is to document the company's quality system, to instruct and guide employees whose actions affect product quality, and to inform the company's customers what controls are implemented to assure product quality.

COO/GM Colin McClennan

Quality Manager: Thomas A. Murphy

QUALITY MANAGEMENT SYSTEM

4.0 CONTEXT OF THE ORGANIZATION

4.1 Understanding the Organization and Its Context

EVANS CAPACITOR COMPANY manufactures high energy density capacitors and capacitor assemblies for demanding defense and aerospace applications. Typical applications replace standard military capacitors, or augment batteries and power supplies where size, weight, reliability, and quality are important factors of component selection. Our products are electrolytic-electrochemical Hybrid Capacitors, Capattery® electrochemical capacitors, and capacitor modules.

EVANS CAPACITOR COMPANY has a documented and implemented quality management system that satisfies the requirements of AS9100D. The quality system is documented in the quality policy and objectives, quality manual, operating procedures, work instructions, process procedures, company technical standards, national and international standards, and the production and quality plans. Implementation of the quality system is regularly audited and reviewed. All personnel are aware of, and have access to, relevant QMS documentation and changes. *EVANS CAPACITOR COMPANY* does not outsource any processes.

4.2 Understanding the Needs and Expectations of Interested Parties

The Interested Parties and their requirements that are relevant to the quality management system are:

Customers	Deliver quality products on-time.
Shareholders	Make a profit and strive to increase profit.
Employees	Provide meaningful employment and livelihood.
Suppliers	Communicate requirements and honor contracts.
Statutory Agencies	Follow/obey legal requirements.
Regulatory Agencies	Comply with established regulations.

The company monitors and reviews information about Needs and Expectations from customer meetings, phone conversations, employee meetings, supplier meetings, news, email, and mail.

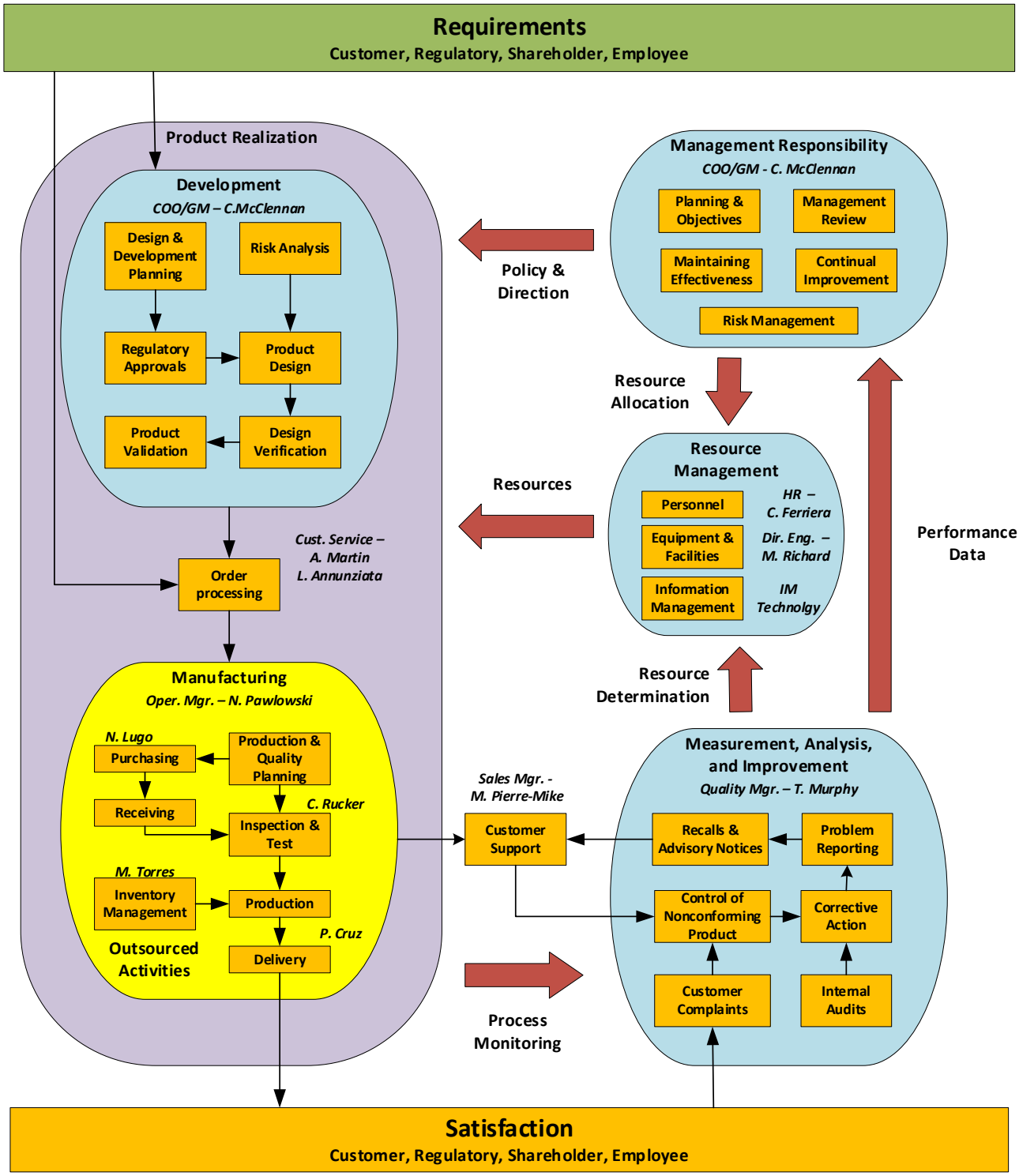
4.3 Determining the Scope of the Quality Management System

As required by AS9100D, the scope was established from the boundaries and applicability of the Quality Management System with consideration for company Context (4.1), the requirements of relevant interested parties (4.2), and the company products and services.

4.4 Quality Management System and Its Processes

4.4.1 Process Input, Output, Sequence, and Interaction.

Process Interaction Matrix



4.4.2 Documented Information

General – The scope of the quality system is defined in the following documents:

- Quality Policy and Objectives,
- Quality Manual **(Level 1)**,
- Operating Procedures **(Level 2)**,
- Work instructions, process procedures and internal standards **(Level 3)**,
- Forms and media used to capture data or information resulting from procedures or work instructions **(Level 4)**,
- Applicable national and international standards,
- Product technical specifications and drawings,
- Production and quality plans

The documents collectively define a quality system that complies with AS9100D.

5.0 LEADERSHIP

5.1 Leadership and Commitment

EVANS CAPACITOR COMPANY is committed to providing our customers with the highest quality products. Our customers have been and will continue to be our number one priority. Our objective is to anticipate tomorrow's needs by improving procedures, equipment, and employee education today. *EVANS CAPACITOR COMPANY* is committed to meeting all applicable statutory and regulatory requirements and the communication of these requirements to all employees. EVANS CAPACITOR COMPANY is committed to providing a safe and rewarding work environment for all employees.

5.1.2 Customer Focus

EVANS CAPACITOR COMPANY ensures that all customer contracts, customer purchase orders, and requests for quotations are reviewed to assess if the customer's requirements are adequately defined and are well understood, and if the company has the capability to meet the contract requirements. It is *EVANS CAPACITOR COMPANY'*s goal to not only meet all customer requirements, but to exceed customer expectations.

5.2 Policy

5.2.1 Quality Policy

EVANS CAPACITOR COMPANY recognizes the need for the highest quality products and continuous process improvement. We will make these improvements consistent with our product requirements and customer inputs. Our customers have been and will continue to be our number one priority. Our objective is to anticipate our customer's needs by improving procedures, equipment, and employee education today. This commitment ensures that our customers will receive defect free products that are delivered on time.

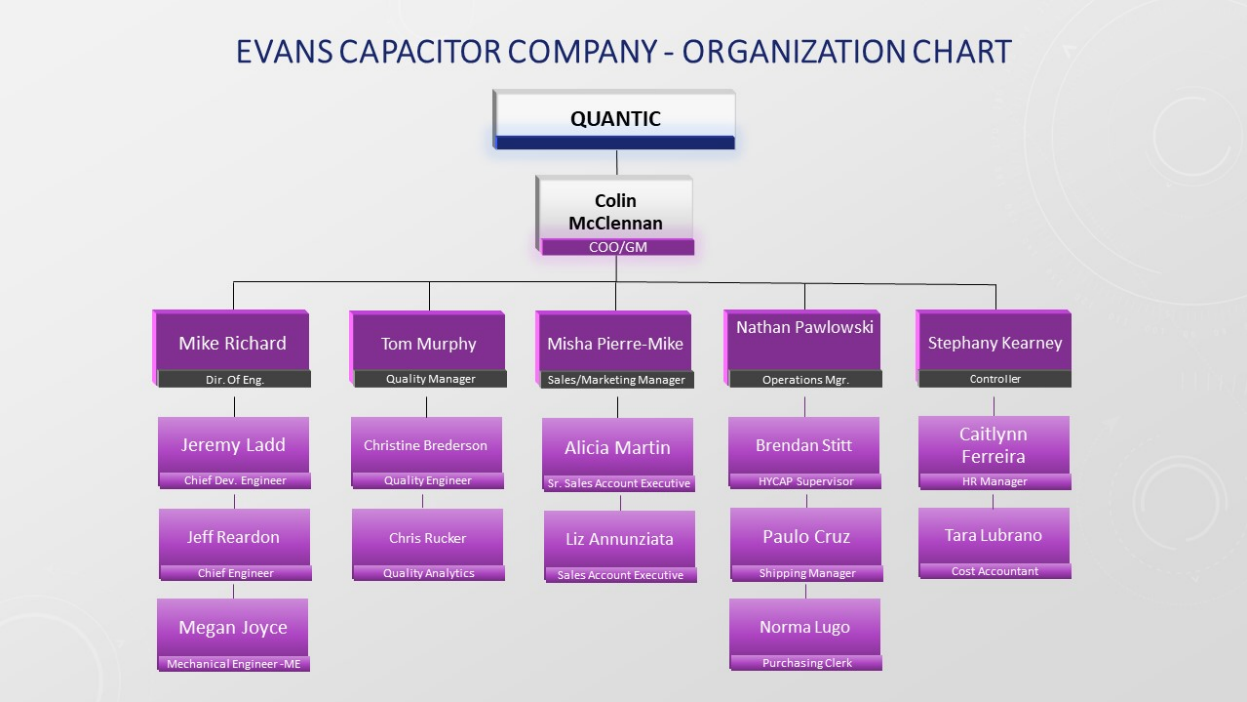
Colin McClennan
COO/GM

5.2.2 Communicating the Quality Policy

The COO/GM of *EVANS CAPACITOR COMPANY* has formulated the quality policy and objective. This policy and objective are explained and discussed at the general orientation training given to all existing and new employees. The policy is also posted in conspicuous locations throughout the company.

5.3 Organizational Roles, Responsibilities, and Authorities

Organization



5.3.1 Responsibility and Authority

5.3.1.1 COO/GM

- Formulates the quality policy,
- Initiates and supervises the quality system,
- Provides resources necessary to maintain the system,
- Conducts management reviews of the quality system,
- Risk identification, assessment, management of actions to mitigate risks, and acceptance of risks.

Authority: Full authority

5.3.1.2 Controller

- Financial Authority,
- Credit and Collections,
- Accounting,
- Provides resources necessary to support production,
- Defines manufacturing personnel qualification requirements,
- Implements measures to motivate personnel,
- Conducts training and reviews the training needs of all employees,
- Determines production personnel, equipment, and material requirements,
- Controls and monitors processes,
- Maintains production equipment and Facility, administrates storage areas
- Controls handling, storage, preservation, and transportation of all materials.
- Provides Production and Business Operations Oversight
- Production planning and control,
- Conducts management reviews of the quality system.
- Risk identification, assessment, management of actions to mitigate risks, and acceptance of risks.

Authority: Personnel, Payroll, Accounts Receivable and Payable

5.3.1.3 Human Resources Manager

- Defines manufacturing personnel qualification requirements,
- Implements measures to motivate personnel,
- Conducts training and reviews the training needs of all employees,
- Determines production personnel, equipment, and material requirements,
- Conducts initial training of all employees,
- Hires all personnel and administers benefit package.

Authority: Training, Hiring/Dismissing Personnel, Payroll

5.3.1.4 Purchasing Clerk

- Selects and qualifies suppliers and subcontractors,
- Prepares and approves purchasing documents,
- Monitors and assesses supplier performance,

Authority: Purchase Orders, Supplier Reports

5.3.1.5 Director of Operations

- Provides resources necessary to support production,
- Defines manufacturing personnel qualification requirements,
- Implements measures to motivate personnel,
- Determines production personnel, equipment, and material requirements,
- Controls and monitors processes,
- Maintains production equipment and Facility, administrates storage areas
- Controls handling, storage, preservation, and transportation of all materials.
- Provides Production Operations Oversight
- Production planning and control,
- Risk identification, assessment, management of actions to mitigate risks, and acceptance of risks.

Authority: Production and Delivery

5.3.1.6 Sales/Marketing Manager

- Negotiate customer contracts,
- Generates customer quotations,
- Represents company and quality system to customers,
- Conducts contract reviews and quotations,
- Provides customer liaison and service,
- Handles customer complaints.
- Advertises and promotes company's products emphasizing their quality aspects,
- Publishes functional specifications of products and associated services (product briefs),
- Risk identification, assessment, management of actions to mitigate risks, and acceptance of risks.

Authority: Sales and Marketing

5.3.1.7 Quality Manager

- Establishes, maintains, and reports on the quality management system,
- Audits implementation of the quality system,
- Initiates requests for, and follows up on, corrective actions,
- Carries out supplier quality surveys and audits,
- Monitors supplier quality performance,
- Performs inspections and testing in accordance with the quality plans,
- Handles nonconforming products,
- Maintains inspection records,
- Defines workmanship standards,
- Maintains calibration records,
- Coordinates document control activities,
- Maintains and calibrates measuring and test equipment
- Information Technology

Authority: Material, Product, and Process Approval. Quality System Approval

5.3.1.8 Director of Engineering

- Establishes, maintains, and reports on the facilities and equipment,
- Provides equipment and facility resources necessary to support production,
- Maintains equipment and maintenance records.
- Provides Engineering Operations Oversight

Authority: Equipment and Facilities

5.3.1.9 Chief Engineers

- Research and Design of new products,
- Initiates design reviews,
- Verifies and tests the designs,
- Documents designs,
- Performs production engineering,
- Qualifies new suppliers and components,
- Collects field performance and reliability data.

Authority: Design, Material, and Process Approval

5.3.1.10 Management Representative

EVANS CAPACITOR COMPANY appoints as the Management Representative, the Quality Manager. The Quality Manager has the authority and responsibility to report on the performance of the Quality System, to ensure that the quality management system is maintained, that its efficiency is continuously improved, and that the system always complies with the requirements of the AS9100D standard. The Quality Manager is also responsible for the promotion of the awareness of customer requirements throughout the company.

5.3.2 Internal Communication

The COO/GM shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. Interaction (and communication) between process is shown on page 7.

6.0 PLANNING

6.1 Actions to Address Risk and Opportunities

EVANS CAPACITOR COMPANY evaluates all risks and opportunities during contract review and prior to the acceptance of any purchase order. The company considers issues referred to in 4.1, Understanding the Organization and Its Context, and the requirements referred to in 4.2, Understanding the Needs and Expectations of Interested Parties. The COO/GM is responsible for Risk Management.

Risk is evaluated in the following areas:

1. Business risk (financial, environmental, etc.);
2. Performance Risk (Product offering through Production & delivery);
3. Facilities Risk (damage to building, equipment, data, etc.);

The COO/GM shall define risk in these areas, through:

1. Probability of Occurrence;
2. Consequence of Occurrence;
3. Acceptable level of consequence;

The COO/GM shall Outline action plan to:

1. Quantify Risks based on above;
2. Develop process and procedures to mitigate risk;
3. Determine performance against acceptable level of Risk;
4. Report to management review;

6.2 Quality Objectives and Planning to Achieve Them

6.2.1 The organization shall establish quality objectives at relevant functions, 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.

The organization shall maintain documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, the organization shall determine:

a. What will be done;

b. What resources will be required;

c. Who will be responsible;

d. When will it be completed;

e. How the results will be evaluated.

6.3 Planning of Changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner. The organization shall consider:

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.

7.0 SUPPORT

7.1 Resources

7.1.1 General

The COO/GM has the responsibility and authority to determine and provide the resources (in the form of personnel, equipment, infrastructure, and environment) needed to 1.) Implement and maintain the quality management system and continually improve its effectiveness, and 2.) Enhance customer satisfaction by meeting customer requirements.

7.1.2 People

The COO/GM has the responsibility and authority to determine and provide the personnel resources needed for product design and production, quality system implantation and maintenance, and customer service and satisfaction.

7.1.3 Infrastructure

The COO/GM is responsible for determining, providing, and maintaining the infrastructure required for the operation of company processes and to achieve conformity of products and services. Infrastructure includes:

a. buildings, workspace, and associated utilities;

b. process equipment (both hardware and software);

c. supporting services (such as transportation, information, and communication).

7.1.4 Environment for the Operation of Processes

The COO/GM is responsible for determining, providing, and maintaining the environment required for the operation of company processes and to achieve conformity of products and services. A suitable environment includes:

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

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

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

7.1.5 Monitoring and Measuring Resources

The COO/GM is responsible for determining, providing, 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. The company shall 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.

The company shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.6 Organizational Knowledge

The COO/GM is responsible for determining the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

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

When addressing changing needs and trends, the company shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

The COO/GM shall:

a. Determine the necessary competence of person(s) doing work under its control that affects the 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.

The competence of all production employees is assessed once a year by the Human Resources Manager to determine if their qualifications are adequate and if they need to be supplemented by additional training.

7.3 Awareness

The COO/GM shall insure that persons doing work under the organizations 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 to 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

The COO/GM shall 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.

7.5 Documented Information

7.5.1 General - Quality Manual

The quality manual is divided into sections corresponding to quality system requirements of the AS9100D standard. The purpose of the quality manual is to document the company's quality system, to instruct and guide employees whose actions affect product quality, and to inform the company's customers what controls are implemented to assure product quality.

7.5.2 Creating and Updating

All documents will include appropriate identification and description, format, and review and approval.

7.5.3 Control of Documented Information

The purpose and scope of quality system documents are defined. All documents and data are reviewed and approved prior to issue. The Quality Manager is responsible for coordinating, enforcing, and auditing the document and data control related activities. Evans Capacitor Company will coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

7.5.3.1 Appropriate documents are available at locations where they are intended to be used. All documents are protected, legible, and readily identifiable. Unreadable and unidentifiable documents are removed and replaced.

7.5.3.2 Documents are distributed where required and access is controlled. Documents are adequately stored and preserved. Documents are revision controlled through ECO approval (Exception: Quality Manual and Procedures approved on the document itself). Obsolete documents are removed from points of use.

Necessary external documented information is identified as appropriate and controlled.

Electronic documented information is protected from loss, unauthorized changes, unintended alterations, corruption, and physical damage.

8.0 OPERATION

8.1 Operational Planning and Control

Evans Capacitor Company shall plan, implement, and control the processes needed to meet the requirements for the provision of products and services, and to implement the actions determined in clause 6, by:

a. Determining the requirements for the products and services, including:
   - Personal and product safety;
   - Producibility and inspectability;
   - Reliability, availability, and maintainability;
   - Suitability of parts and materials used in the product;
   - 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.

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 processes in accordance with the criteria;

e. Determining, maintaining, and retaining documented information to the extent necessary:
   - To have confidence that the process has been carried out as planned;
   - To demonstrate the conformity of products and services to their requirements;

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

g. Engaging representatives of affected organization functions for operational planning and control;

h. Determining the process and resources to support the use and maintenance of the products and services;

i. Determining the products and services to be obtained from external providers;

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

8.1.1 Operational Risk Management

The COO/GM is responsible for planning, implementing, and controlling the process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to the organization and the product and services:

a. Assignment of responsibilities for operational risk management;

b. Definition of risk assessment criteria (e.g. likelihood, consequences, risk acceptance);

c. Identification, assessment, and communication of risks throughout operations;

d. Identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;

e. Acceptance of risks remaining after implementation of mitigating actions.

8.1.2 Configuration Management

The COO/GM is responsible for planning, implementing, and controlling the process for configuration management as appropriate to the organization and its products and services in order to ensure the identification 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, verification, validation and acceptance documentation) is consistent with the actual attributes of the product and services.

8.1.3 Product Safety

The COO/GM is responsible for planning, implementing, and controlling the processes needed to assure product safety during the entire product life cycle, as appropriate to the organization and the product.

8.1.4 Prevention of Counterfeit Parts

The COO/GM is responsible for planning, implementing, and controlling the processes needed for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer during the entire product life cycle, as appropriate to the organization and the product.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

The Sales and Marketing Manager is responsible for communication with customers which 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 Products and Services

The Sales and Marketing Manager is responsible for determining the requirements for the products and services to be offered to customers, and they shall ensure that:

a. The requirements for the product and services are defined, including:
   - Any applicable statutory and regulatory requirements;
   - Those required by the company;

b. The company can meet the claims for the products and services it offers;

c. Special requirements of the products and services are determined;

d. Operational risks (e.g. new technology, ability and capacity to provide, short delivery time frame) have been identified.

8.2.3 Review of the Requirements for Products and Services

8.2.3.1 The Sales and Marketing Manager is responsible for ensuring that the company has the ability to meet the requirements for the products and services to be offered to customers. The company shall conduct a review before committing to supply product and services to the customer, to include:

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

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

c. Requirements specified by the company;

d. Statutory and regulatory requirements applicable to the products and services;

e. Contract or order requirements differing from those previously expressed.

This review shall be coordinated with applicable functions of the company.

If upon review it is determined that some of the customer requirements cannot be met, or can only partially be met, the company shall negotiate a mutually acceptable requirement with the customer.

The Sales and Marketing Manager is responsible for ensuring that contract or order requirements differing from those previously defined are resolved.

The customer requirements shall be confirmed by the company before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.2 The company shall 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

The company shall 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

8.3.1 General

The Director of Engineering is responsible for establishing, implementing, and maintaining a design and development process that is appropriate to ensure the subsequent provision of product and services.

8.3.2 Design and Development Planning

In determining the stages and controls for design and development, the company shall consider:

a. The nature, duration, and complexity of the design and development activities;

b. The required process stages, including applicable design and development reviews;

c. The required design and development verification and validation activities;

d. The responsibilities and authorities involved in the design and development process;

e. The internal and external resource needs for the design and development of products and services;

f. The need to control interfaces between persons involved in the design and development process;

g. The need for involvement of customers and users in the design and development process;

h. The requirements for subsequent provision of products and services;

i. The level of control expected for the design and development process by customers and other relevant interested parties;

j. The documented information needed to demonstrate that design and development requirements have been met.

When appropriate, the company shall divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, and inputs and outputs.

Design and development planning shall consider the ability to provide, verify, test, and maintain products and services (reference output of 8.1 a).

8.3.3 Design and Development Inputs

The Director of Engineering shall be responsible for determining the requirements essential for the specific types of products and services to be designed and developed. They will consider:

a. Functional and performance requirements;

b. Information derived from previous similar design and development activities;

c. Statutory and regulatory requirements;

d. Standards or codes of practice that the company has committed to implement;

e. Potential consequences of failure due to the nature of the products and services;

f. When applicable, the potential consequences of obsolescence (e.g. materials, processes, components, equipment, products).

Inputs shall be adequate for design and development purposes, complete, and unambiguous.

Conflicting design and development inputs shall be resolved.

The company will retain documented information on design and development inputs.

8.3.4 Design and Development Controls

The Director of Engineering is responsible for applying controls to the design and development process to ensure that:

a. The results to be achieved are defined;

b. Reviews are conducted to evaluate the ability of results of design and development to meet requirements;

c. Verification activities are conducted to ensure that the design and development outputs meet the input requirements;

d. Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;

e. Any necessary actions are taken on problems determined during the reviews, or verification and validation activities;

f. Documented information of these activities is retained;

g. Progression to the next stage is authorized.

Participants in design and development reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed.

8.3.4.1 When tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure the following:

a. Test plans or specifications identify the test item being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria;

b. Test procedures describe the test methods to be used, how to perform the test, and how to record the results;

c. The correct configuration of the item is submitted for the test;

d. The requirements of the test plan and the test procedures are observed;

e. The acceptance criteria are met.

Monitoring and measuring devices used for testing shall be controlled as defined in clause 7.1.5.

At the completion of design and development, the company shall ensure that reports, calculations, test results, etc., are able to demonstrate that the design for the product or service meets the specification requirements for all identified operating conditions.

8.3.5 Design and Development Outputs

The Director of Engineering shall be responsible for ensuring that design and development outputs:

a. Meet the input requirements;

b. Are adequate for the subsequent processes for the provision of products and services;

c. Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

d. Specify the characteristics of products and services that are essential for their intended purpose and their safe and proper provision;

e. Specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items;

f. Are approved authorized person(s) prior to release.

The company shall define the data required to allow the product to be identified, manufactured, verified, used, and maintained.

The company shall retain documented information on design and development outputs.

8.3.6 Design and Development Changes

The Director of Engineering shall be responsible for identifying, reviewing, and controlling changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The company shall implement a process with criteria for notifying its customer, prior to implementation, about changes that affect customer requirements.

The company shall retain documented information on:

a. Design and development change;
b. The results of reviews;
c. The authorization of the changes;
d. The actions taken to prevent adverse impacts.

Design and development changes shall be controlled in accordance with the configuration management process requirements.

8.4 Control of Externally Provided Processes, Products, and Services

8.4.1 General

The Controller and the Quality Manager shall be responsible for ensuring that externally provide processes, products, and services, including from sources defined by the customer, conform to requirements.

The company shall ensure, when required. That customer-designated or approved external providers, including process sources (e.g. special processes), are used.

The company shall identify and manage the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers.

The company shall require that external providers apply appropriate controls to their sub-tier external providers, to ensure that requirements are met.

The company shall determine 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 company's own products and services;
b. Products and services are provided directly to the customer(s) by external providers on the company's behalf;
c. A process, or part of a process, is provided by an external provider because of a decision by the company.

The company shall 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. The company shall retain documented information of these activities and any necessary action arising from the evaluations.

8.4.1.1 The company 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 (Approved Supplier List) of its external providers that includes approval status and the scope of approval;

c. Periodically review (during Management Reviews) external provider performance including process, 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 requirements for controlling documented information created by and/or retained by external providers.

8.4.2 Type and Extent of Control

The Controller and the Quality Manager shall be responsible for ensuring that externally provide processes, products, and services do not adversely affect the company's ability to consistently deliver conforming products and services to its customers.

The company 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;

c. The results of the periodic review of external provider performance (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.

Verification activities of externally provided processes, products, and services shall be performed according to risks identified by the company. These shall 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 shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

When the company delegates verification activities to the external provider, the scope and requirements for delegation shall be defined and a register of delegations shall be maintained. The company shall periodically monitor the external provider's delegated verification activities.

When external provider test reports are utilized to verify externally provided products, the company shall implement a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or company has identified raw material as a significant operational risk (e.g. critical items), the company shall implement a process to validate the accuracy of test reports.

8.4.3 Information for External Providers

The Controller and the Quality Manager shall be responsible for ensuring the adequacy of requirements prior to their communication to the external provider.

The company shall communicate to external providers its requirements for:

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

b. The approval of:
    1. Products and services;
    2. Methods, processes, and equipment;
    3. The release of products and services;

c. Competence, including any required qualification of persons;

d. The external providers' interactions with the company;

e. Control and monitoring of the external providers' performance to be applied by the company;

f. Verification or validation activities that the company, or its customer, intends to perform at the external providers' premises;

g. Design and development control;

h. Special requirements, critical items, or 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 company;

k. The need to:
   - Implement a quality management system;
   - Use customer-designated or approved external providers, including process sources (e.g. special processes);
   - Notify the company of nonconforming processes, products, or services and obtain approval for their disposition;
   - Prevent the use of counterfeit parts (see 8.1.4);
   - Notify the company of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the company's approval;
   - Flow down to external applicable requirements including customer requirements;
   - Provide test specimens for design approval, inspection/verification, investigation, or auditing;
   - Retain documented information, including retention periods and disposition requirements;

l. The right to access by the company, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;

m. Ensuring that persons are aware of:
   - Their contribution to product or service conformity;
   - Their contribution to product safety;
   - The importance of ethical behavior.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

The Operations Director is responsible for implementing production and service provision under controlled conditions.

Controlled conditions shall include, as applicable:

a. The availability of documented information that defines:
    i. The characteristics of products to be produced, the services to be provided, or the activities to be performed;
    ii. 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;
    i. Ensuring that documented information for monitoring and measurement activity for product acceptance includes:
        1. Criteria for acceptance and rejection;
        2. Where in the sequence verification operations are to be performed;
        3. Measurement results to be retained (at a minimum an indication of acceptance or rejection);
        4. Any specific monitoring and measurement equipment required and instructions associated with their use;
    ii. 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 (i.e., matching the sampling plan to the criticality of the product and to the process capability).

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 the processes for production and service provision, where the output cannot be verified by subsequent monitoring or measurement (Special Processes);

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 during production (e.g., parts quantities, split orders, nonconforming product);

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

l. The determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);

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

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

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

p. The control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (7.1.3);

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

8.5.1.1 Control of Equipment, Tools, and Software Programs

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

8.5.1.2 Validation and Control of Special Processes

For processes where the resulting output cannot be verified by subsequent monitoring or measurement, the company shall establish arrangements for these processes including as applicable:

a. Definition of criteria for the review and approval of the processes;

b. Determination of conditions to maintain approval;

c. Approval of facilities and equipment;

d. Qualification of persons;

e. Use of specific methods and procedures for implementation and monitoring the processes;

f. Requirements for documented information to be retained.

8.5.1.3 Production Process Verification

The company shall implement production process verification activities to ensure the production process is able to produce products that meet requirements.

The company shall use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements. This activity (First Article Inspection or FAI) shall be repeated when changes occur that invalidate the original result (e.g., engineering changes, production process changes, tooling changes).

The company will retain documented information on the results of production process verification.

8.5.2 Identification and Traceability

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

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

The company 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 company shall establish controls for the media.

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

8.5.3 Property Belonging to Customers or External Providers

The company shall exercise care with property belonging to customers or external providers while it is under the company's control or being used by the company.

The company shall identify, verify, protect, and safeguard customers' or external providers' property provided for use or incorporation into products and services.

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

8.5.4 Preservation

The company shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

Preservation of outputs shall 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

The company shall meet requirements for post-delivery activities associated with products and services.

In determining the extent of post-delivery activities that are required, the company shall 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. Collection and analysis of in-service data;

g. Control, updating, and provision of technical documentation relating to product use, maintenance, and repair;

h. Controls required for work undertaken external to the company;

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

When problems are detected after delivery, the company shall take appropriate action including investigation and reporting.

8.5.6 Control of Changes

The company shall 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 shall be identified.

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

8.6 Release of Products and Services

The company shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

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

The company shall retain documented information on the release of products and services. The documented information shall include:

a. Evidence of conformity with acceptance criteria;

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

When require to demonstrate product qualification, the company shall ensure that retained documented information provides evidence that the products and services meet the defined requirements.

The company shall 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 The company shall insure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The company shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

The company's nonconformity control process shall 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 product 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).

The company shall deal with nonconforming output 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 by a relevant authority and, when applicable, by the customer.

Dispositions of use-as-is or repair for the acceptance of nonconforming products shall only be implemented:

- After approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;

- After authorization by the customer, if the nonconformity results in a departure from the contract requirements.

Products 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 The company shall retain documented information that:

a. Describes the nonconformity;

b. Describes the actions taken;

c. Describes any concessions obtained;

d. Identifies the authority deciding the action in respect of the nonconformity.

9.0 PERFORMANCE EVALUATION

9.1 Monitoring, Measurement, Analysis, and Evaluation

9.1.1 General

The company shall determine:

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 shall be performed;

d. When the results from monitoring and measurement shall be analyzed and evaluated.

The company shall evaluate the performance and the effectiveness of the quality management system.

The company shall retain appropriate documented information as evidence of the results.

9.1.2 Customer Satisfaction

The company shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The company shall determine the methods for obtaining, monitoring, and reviewing this information.

Information to be monitored and used for evaluation of customer satisfaction shall include, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. The company shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations and assess the effectiveness of the results.

9.1.3 Analysis and Evaluation

The company shall analyze and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used to evaluate:

a. Conformity of products and services;
b. The degree of customer satisfaction;
c. The performance and effectiveness of the quality management system;
d. If planning has been implemented effectively;
e. The effectiveness of actions taken to address risk and opportunities;
f. The performance of external providers;
g. The need for improvements to the quality management system.

9.2 Internal Audit

9.2.1 The company shall conduct internal audits at planned intervals to provide information on whether the quality management system;

1) Conforms to:
    a. The company's own requirements for its quality management system;
    b. The requirements of AS9100 D;
2) Is effectively implemented and maintained.

9.2.2 The company shall:

a. Plan, establish, implement, and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements, and reporting, which shall take into consideration the importance of processes concerned, changes affecting the company, 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 audits are reported to relevant management;
e. Take appropriate correction and corrective actions without undue delay;
f. Retain documented information as evidence of the implementation of the audit program and the audit results.

9.3 Management Review

9.3.1 General

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

9.3.2 Management Review Inputs

The management review shall 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:

    a. Customer satisfaction and feedback from relevant interested parties;
    b. The extent to which quality objectives have been met;
    c. Process performance and conformity of product and services;
    d. Nonconformities and corrective actions;
    e. Monitoring and measurement results;
    f. Audit results;
    g. The performance of external providers;
    h. On-time delivery performance;

d. The adequacy of resources;

e. The effectiveness of actions taken to address risk and opportunities (see 6.1);

f. Opportunities for improvement.

9.3.3 Management Review Outputs

The outputs of the management review shall 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.

The company shall retain documented information as evidence of the results of management reviews.

10.0 IMPROVEMENT

10.1 General

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

These shall include:

a. Improving products and services to meet the requirements as well as address future needs and expectations;

b. Correcting, preventing, or reducing undesired effects;

c. Improving the performance and effectiveness of the quality management system;

10.2 Nonconformity and Corrective Action

10.2.1 When a nonconformity occurs, including any arising from complaints, the company 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, including, as applicable, those related to human factors;

3. Determining if similar nonconformities exist, or could potentially occur;

c. Implement and action needed;

d. Review the effectiveness of any corrective action(s) 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.

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

The company shall maintain documented information that defines the nonconformity and corrective action management processes.

10.2.2 The company shall retain documented information as evidence of:

a. The nature of the nonconformities and any subsequent actions taken;

b. The results of any corrective action.

10.3 Continual Improvement

The company shall continually improve the stability, adequacy, and effectiveness of the quality management system.

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

The company shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.