



**DELTA**  
SYSTEMS

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# Quality Systems Manual

Compliant with ISO 9001:2015



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Quality Systems Manual – Revision History

## 0. Revision History

Rev.	Description of Change	Revised By:	Date
~	Initial Release	C. Mason	03/12/2010
A	Review and update- Purchasing - verified for addition of supply web	C. Mason	02/07/2011
B	Fixed Typo	K. Lester	12/12/2011
C	Fixed Typo 87,000 was 87,0000	K. Lester	03/12/2012
D	Miscellaneous verbiage updated throughout document	B. Litvak	04/19/2013
E	Corrected ISO 9001:2003 to ISO 9001:2008 and ISO 13485:2008 to ISO 13485:2008	M. Haessly	05/03/2013
F	Updated Quality Policy and clarified various sections	M. Haessly	03/03/2014
7	Total rewrite of Version 6 to ensure compliance with ISO 9001:2008 With Design, ISO 13485:2003 Without Design and 21 CFR Part(s) 820 Quality System Regulation	B. Litvak K. Lester	10/28/2014
8	Updated various sections based upon IAR-20150302-1	M. Haessly	4/1/2015
9	Update based upon Smithers audit findings - Smithers Quality Assessment - CAR #4035-Q-757 - 24Surv - 001	M. Haessly	4/21/2015
10	Updated for ISO 9001:2015	M. Haessly	03/02/2017
11	Corrected reference in section 8.5 to eliminate obsolete SOP-8.5.1.002	M. Haessly	03/07/2017
12	Added Quality Scope statement and Process Map	M. Haessly	03/13/2017
13	Updated to new Company Logo	M. Haessly	04/10/2018



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Quality Systems Manual – Section 1 - Document Holders

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## **1. Document Holders:**

### **1.1. FRM-2.0.0 Document Holder Log**



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Quality Systems Manual – Section 2 - Company Vision Statement

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## 2. Company Vision Statement

To be the premier global supplier to the Outdoor Power Equipment Industry, building upon a legacy as an innovator and focusing on leading electrical system technologies and switches of the future that improve performance, safety, and user experience.



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Quality Systems Manual – Section 3 - Company Mission Statement

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### 3. Company Mission Statement and Core Values

#### 3.1. Quality Management Scope

Designs and manufactures electronics, electromechanical switches, controllers, metal stamping, plastic molded injection components and other devices for rugged environments for OEMs. In addition, a contract manufacturer with design services for electronics, electromechanical switches and controllers.

#### 3.2. Mission Statement

We will consistently deliver quality products and services that exceed our customers' expectations, while providing an environment to attract, nurture, empower and retain outstanding people and generate a favorable return for our stakeholders.

#### 3.3. Delta Core Values

##### 3.3.1. Strategic Discipline

- A. People are Delta's greatest asset
- B. We honor a culture of integrity, communication, and service
- C. We treat all people with purpose, trust, dignity, and respect

##### 3.3.2. Strategic Implementation

- A. We strive to convert adversity into opportunity
- B. We accept uncertainty, seek solutions, take calculated risks and encourage positive change
- C. We admit mistakes, learn from them, and make amends

##### 3.3.3. Strategic Direction

- A. Integrity is our #1 value
- B. We apply hard work, responsibility and tenacity
- C. We steward our legacy and hold ourselves and each other accountable for excellence



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## 4. Context of Delta Systems

### 4.1. Understanding Delta Systems and its context

Delta Systems 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.

Delta Systems monitors and reviews information about these external and internal issues.

Issues can include positive and negative factors or conditions for consideration.

Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of Delta Systems.

### 4.2. Understanding the needs and expectations of interested parties

Due to their effect or potential effect on Delta System's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, Delta Systems has determined:

- the interested parties that are relevant to the quality management system;

- the requirements of these interested parties that are relevant to the quality management system. Delta Systems monitors and reviews information about these interested parties and their relevant requirements.

### 4.3. Determining the scope of the quality management system

Delta Systems has determined the boundaries and applicability of the quality management system establishing its scope.

When determining this scope, Delta Systems considered:

- the external and internal issues;

- the requirements of relevant interested parties;

- the products and services of Delta Systems.

Delta Systems has applied all the requirements of this International Standard if they are applicable within the determined scope of the quality management system.





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The scope of Delta Systems's quality management system is be available and is maintained in the document control system. The scope of the QMS is stated on our Quality Management ISO 9001:2015 certification.

state the types of products and services covered, and provide justification for any requirement of this International Standard that Delta Systems 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 Delta Systems's 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. Delta Systems has established, and implemented, a quality management system.

This system is maintained and continually improved and includes the processes needed and their interactions, in accordance with the requirements of the ISO 9001:2015 International Standard.

Delta Systems has determined the processes needed for the quality management system and the application throughout Delta Systems, and has:

- determined the inputs required and the outputs expected from its processes;
- determined the sequence and interaction of its processes;
- determined and has applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of its processes;
- determined the resources needed for the processes and ensure their availability;
- assigned the responsibilities and authorities for these processes;
- addressed the risks and opportunities as determined in accordance with the requirements of the ISO 9001:2015 standard
- evaluated the processes and implemented any changes needed to ensure that these processes achieve their intended results;
- improved the processes and the quality management system.

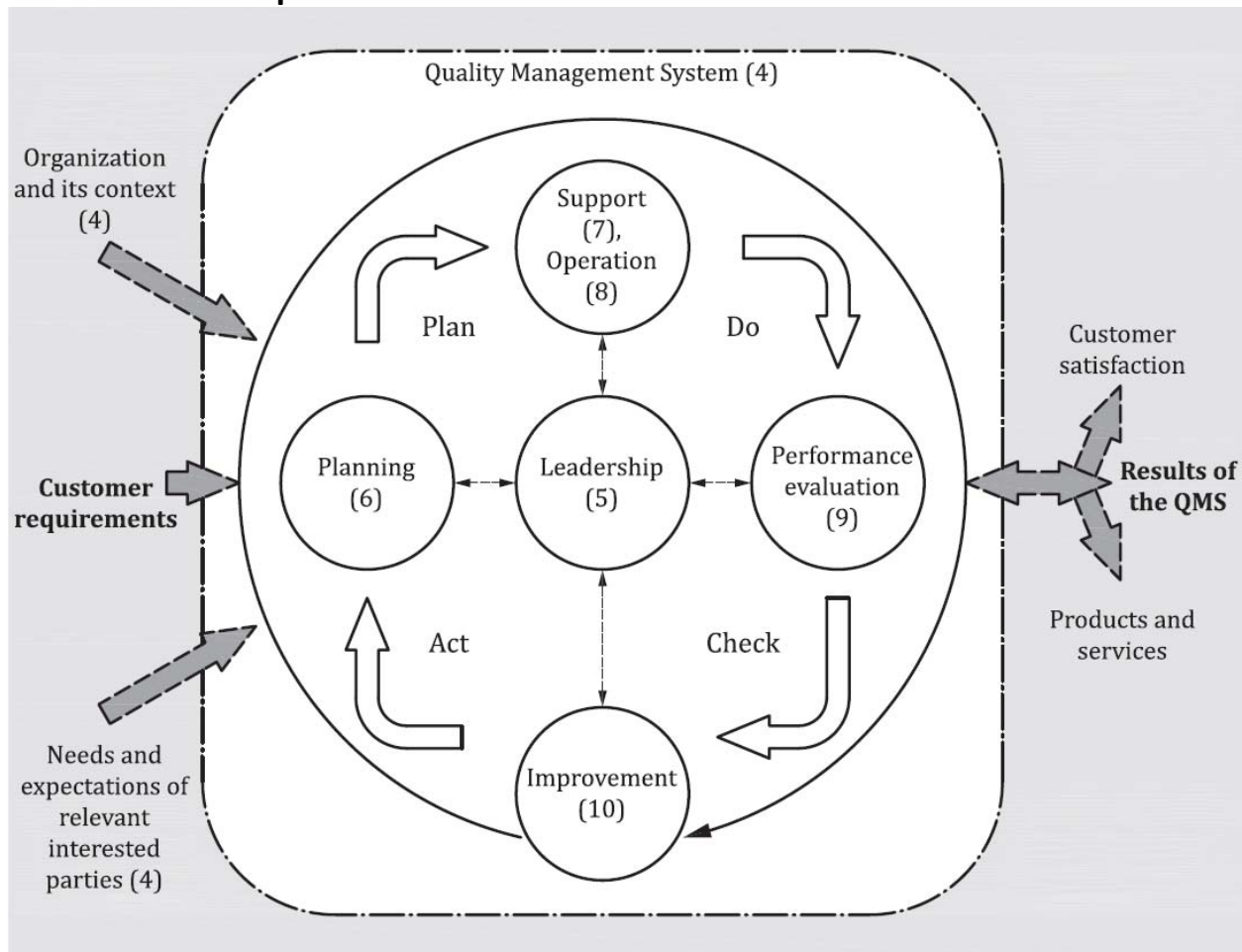
### 4.4.2.

To the extent necessary, Delta Systems has:

- maintained documented information to support the operation of its processes;

retained documented information to have confidence that the processes are being carried out as planned.

## 4.5. Process Map



REFERENCE: SOP-4.0.0.001 - Context of the Organization

## 5. Leadership

### 5.1. Leadership and commitment

#### 5.1.1. General

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

taking accountability for the effectiveness of the quality management system;

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 Delta Systems;

ensuring the integration of the quality management system requirements into Delta Systems's business processes;

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

ensuring that the resources needed for the quality management system are available;

communicating the importance of effective quality management and of conforming to the quality management system requirements;

ensuring that the quality management system achieves its intended results;

engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;

promoting improvement;

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:

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

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

the focus on enhancing customer satisfaction is maintained.

## **5.2. Policy**

### **5.2.1. Establishing the quality policy**

Top management has established, implemented and maintains a quality policy that:

is appropriate to the purpose and context of Delta Systems and supports its strategic direction;

provides a framework for setting quality objectives;

includes a commitment to satisfy applicable requirements;

includes a commitment to continual improvement of the quality management system.



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#### 5.2.2. Communicating the quality policy

The quality policy is:

- available and is maintained as documented information;
- is communicated, understood and applied within Delta Systems;
- is available to relevant interested parties, as appropriate.

#### 5.3. Organizational roles, responsibilities and authorities

Top management has ensured that the responsibilities and authorities for relevant roles are assigned, communicated and understood within Delta Systems.

Top management has assigned the responsibility and authority for:

- ensuring that the quality management system conforms to the requirements of this International Standard;
- ensuring that the processes are delivering their intended outputs;
- reporting on the performance of the quality management system and on opportunities for improvement to top management;
- ensuring the promotion of customer focus throughout Delta Systems;
- ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

REFERENCE: SOP-5.0.0.001 - Leadership

## 6. 6 Planning

### 6.1. Actions to address risks and opportunities

#### 6.1.1.

When planning for the quality management system, Delta Systems has considered the issues referred to in ISO 9001:2015 Element 4.1 and the requirements referred to in ISO 9001:2015 Element 4.2 and determined the risks and opportunities that need to be addressed to:

- give assurance that the quality management system can achieve its intended result(s);
- enhance desirable effects;
- prevent, or reduce, undesired effects;
- achieve improvement.

#### 6.1.2.

Delta Systems has planned:

actions to address these risks and opportunities;

how to:

integrate and implement the actions into its quality management system processes (per ISO 9001:2015 Element 4.4);

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.

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

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

## **6.2. Quality objectives and planning to achieve them**

### **6.2.1.**

Delta Systems has established quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives :

are consistent with the quality policy;

are measurable;

take into account applicable requirements;

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

are monitored;

are communicated;

are updated as appropriate.

Delta Systems maintains documented information on the quality objectives.

### **6.2.2.**

When planning how to achieve its quality objectives, Delta Systems has determined:

what will be done;

- what resources will be required;
- who will be responsible;
- when it will be completed;
- how the results will be evaluated.

### 6.3. Planning of changes

When Delta Systems determines the need for changes to the quality management system, the changes are carried out in a planned manner (see 4.4).

Delta Systems has considered:

- the purpose of the changes and their potential consequences;
- the integrity of the quality management system;
- the availability of resources;
- the allocation or reallocation of responsibilities and authorities.

REFERENCE: SOP-6.0.0.001 - Planning

## 7. Support

### 7.1. Resources

#### 7.1.1. General

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

Delta Systems considers:

- the capabilities of, and constraints on, existing internal resources;
- what needs to be obtained from external providers.

#### 7.1.2. People

Delta Systems determines and provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

#### 7.1.3. Infrastructure

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

Infrastructure can include:

buildings and associated utilities;  
equipment, including hardware and software;  
transportation resources;  
information and communication technology.

#### **7.1.4. Environment for the operation of processes**

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

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

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

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

#### **7.1.5. Monitoring and measuring resources**

##### **7.1.5.1 General**

Delta Systems 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.

Delta Systems ensures that the resources provided:

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

Delta Systems retains the 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 Delta Systems to be an essential part of providing confidence in the validity of measurement results, measuring equipment are:

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;  
identified in order to determine their status;



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safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

Delta Systems 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

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

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

When addressing changing needs and trends, Delta Systems considers its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

Organizational knowledge is knowledge specific to Delta Systems; it is generally gained by experience. It is information that is used and shared to achieve Delta Systems's objectives.

Organizational knowledge can be based on:

internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);

external sources ( e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

## 7.2. Competence

Delta Systems:

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

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

where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

retains appropriate documented information as evidence of competence.

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



### **7.3. Awareness**

Delta Systems ensures that persons doing work under Delta Systems's control are aware of:

- the quality policy;
- relevant quality objectives;
- their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
- the implications of not conforming with the quality management system requirements.

### **7.4. Communication**

Delta Systems determines the internal and external communications relevant to the quality management system, including:

- on what it will communicate;
- when to communicate;
- with whom to communicate;
- how to communicate;
- who communicates.

### **7.5. Documented information**

#### **7.5.1. General**

Delta Systems's quality management system includes:

- documented information required by this International Standard;
- documented information determined by Delta Systems as being necessary for the effectiveness of the quality management system.

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

- the size of organization and its type of activities, processes, products and services;
- the complexity of processes and their interactions;
- the competence of persons.

#### **7.5.2. Creating and updating**

When creating and updating documented information, Delta Systems ensures appropriate:

- identification and description (e.g. a title, date, author, or reference number);

format (e.g. language, software version, graphics) and media (e.g. paper, electronic);  
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 this International

Standard are controlled to ensure:

it is available and suitable for use, where and when it is needed;

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, Delta Systems addresses the following activities, as applicable:

distribution, access, retrieval and use;

storage and preservation, including preservation of legibility;

control of changes (e.g. version control);

retention and disposition.

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

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

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

REFERENCE: SOP-7.1.1.001 - Resources.docx

REFERENCE: SOP-7.1.3.001 - Infrastructure.doc

REFERENCE: SOP-7.1.4.001 - Environment for the Operation of Processes.docx

REFERENCE: SOP-7.1.5.001 - Control of Monitoring and Measuring Resources

REFERENCE: SOP-7.2.0.001 - Knowledge, Competence, Awareness, Communications

REFERENCE: SOP-7.5.1.001 - Documented Information

## 8. Operation

### 8.1. Operational planning and control

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Delta Systems plans, implements and controls the processes (see ISO 9001:2015 Clause 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in ISO 9001:2015 Element Clause 6, by:

- determining the requirements for the products and services;
- establishing criteria for:
  - the processes;
  - the acceptance of products and services;
- determining the resources needed to achieve conformity to the product and service requirements;
- implementing control of the processes in accordance with the criteria;
- determining, maintaining and retaining documented information to the extent necessary:
- to have confidence that the processes have been carried out as planned;
- to demonstrate the conformity of products and services to their requirements.

The output of this planning is suitable for Delta Systems's operations.

Delta Systems controls planned changes and the review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

Delta Systems ensures that outsourced processes are controlled (see 8.4).

## **8.2. Requirements for products and services**

### **8.2.1. Customer communication**

Communication with customers includes:

- providing information relating to products and services;
- handling enquiries, contracts or orders, including changes;
- obtaining customer feedback relating to products and services, including customer complaints;
- handling or controlling customer property;
- establishing specific requirements for contingency actions, when relevant.

### **8.2.2. Determining the requirements for products and services**

When determining the requirements for the products and services to be offered to customers, Delta Systems ensures that:



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the requirements for the products and services are defined, including:  
any applicable statutory and regulatory requirements;  
those considered necessary by Delta Systems;

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

- requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- requirements not stated by the customer, but necessary for the specified or intended use, when known;
- requirements specified by Delta Systems;
- statutory and regulatory requirements applicable to the products and services;
- contract or order requirements differing from those previously expressed.

Delta Systems ensures that contract or order requirements differing from those previously defined are resolved.

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

In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.

8.2.3.2 Delta Systems retains documented information, as applicable:

- on the results of the review;
- on any new requirements for the products and services.

#### **8.2.4. Changes to requirements for products and services**

Delta Systems 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.

### **8.3. Design and development of products and services**

#### **8.3.1. General**



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Delta Systems establishes, implements and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services.

#### **8.3.2. Design and development planning**

In determining the stages and controls for design and development, Delta Systems considers:

- the nature, duration and complexity of the design and development activities;
- the required process stages, including applicable design and development reviews;
- the required design and development verification and validation activities;
- the responsibilities and authorities involved in the design and development process;
- the internal and external resource needs for the design and development of products and services;
- the need to control interfaces between persons involved in the design and development process;
- the need for involvement of customers and users in the design and development process;
- the requirements for subsequent provision of products and services;
- the level of control expected for the design and development process by customers and other relevant interested parties;
- the documented information needed to demonstrate that design and development requirements have been met.

#### **8.3.3. Design and development inputs**

Delta Systems determines the requirements essential for the specific types of products and services to be designed and developed. Delta Systems considers:

- functional and performance requirements;
- information derived from previous similar design and development activities;
- statutory and regulatory requirements;
- standards or codes of practice that Delta Systems has committed to implement;
- potential consequences of failure due to the nature of the products and services. Inputs are adequate for design and development purposes, complete and unambiguous.

Conflicting design and development inputs are resolved.

Delta Systems retains documented information on design and development inputs.

#### **8.3.4. Design and development controls**

Delta Systems applies controls to the design and development process to ensure that:

- the results to be achieved are defined;
- reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
- verification activities are conducted to ensure that the design and development outputs meet the input requirements;
- validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
- any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
- documented information of these activities is retained.

Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of Delta Systems.

#### **8.3.5. Design and development outputs**

Delta Systems ensures that design and development outputs:

- meet the input requirements;
- are adequate for the subsequent processes for the provision of products and services;
- include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
- specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

Delta Systems retains documented information on design and development outputs.

#### **8.3.6. Design and development changes**

Delta Systems identifies, reviews and controls 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.

Delta Systems retains documented information on:

- design and development changes;
- the results of reviews;

the authorization of the changes;  
the actions taken to prevent adverse impacts.

## **8.4. Control of externally provided processes, products and services**

### **8.4.1. General**

Delta Systems ensures that externally provided processes, products and services conform to requirements.

Delta Systems determines the controls to be applied to externally provided processes, products and services when:

- products and services from external providers are intended for incorporation into Delta System's own products and services;

- products and services are provided directly to the customer(s) by external providers on behalf of Delta Systems;

- a process, or part of a process, is provided by an external provider as a result of a decision by Delta Systems.

Delta Systems determines and applies 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. Delta Systems retains documented information of these activities and any necessary actions arising from the evaluations.

### **8.4.2. Type and extent of control**

Delta Systems ensures that externally provided processes, products and services do not adversely affect Delta Systems's ability to consistently deliver conforming products and services to its customers.

Delta Systems:

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

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

- takes into consideration:

  - the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;

  - the effectiveness of the controls applied by the external provider;



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

#### 8.4.3. Information for external providers

Delta Systems ensures the adequacy of requirements prior to their communication to the external provider.

Delta Systems communicates to external providers its requirements for:

- the processes, products and services to be provided;
- the approval of:
  - products and services;
  - methods, processes and equipment;
  - the release of products and services;
  - competence, including any required qualification of persons;
- the external providers' interactions with Delta Systems;
- control and monitoring of the external providers' performance to be applied by Delta Systems;
- verification or validation activities that Delta Systems, or its customer, intends to perform at the external providers' premises.

## 8.5. Production and service provision

### 8.5.1. Control of production and service provision

Delta Systems implements production and service provisions under controlled conditions.

Controlled conditions include, as applicable:

- the availability of documented information that defines:
  - the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
  - the results to be achieved;
  - the availability and use of suitable monitoring and measuring resources;
  - 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;
  - the use of suitable infrastructure and environment for the operation of processes;



the appointment of competent persons, including any required qualification;

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

the implementation of actions to prevent human error;

the implementation of release, delivery and post-delivery activities.

#### **8.5.2. Identification and traceability**

Delta Systems uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

Delta Systems identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

Delta Systems controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability.

#### **8.5.3. Property belonging to customers or external providers**

Delta Systems exercises care with property belonging to customers or external providers while it is under Delta Systems's control or being used by Delta Systems.

Delta Systems identifies, verifies, protects and safeguards customers' or external providers' property provided for use or incorporation into the products and services.

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

Customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

#### **8.5.4. Preservation**

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

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

#### **8.5.5. Post-delivery activities**

Delta Systems meets requirements for post-delivery activities associated with the products and services.



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In determining the extent of post-delivery activities that are required, Delta Systems considers:

- statutory and regulatory requirements;
- the potential undesired consequences associated with its products and services;
- the nature, use and intended lifetime of its products and services;
- customer requirements;
- customer feedback.

Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

#### 8.5.6. Control of changes

Delta Systems reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

Delta Systems 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.

### 8.6. Release of products and services

Delta Systems implements planned arrangements, 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.

Delta Systems retains documented information on the release of products and services. The documented information includes:

- evidence of conformity with the acceptance criteria;
- traceability to the person(s) authorizing the release.

### 8.7. Control of nonconforming outputs

#### 8.7.1. Delta Systems ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

Delta Systems 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.

Delta Systems deals with nonconforming outputs in one or more of the following ways:

- correction;
- segregation, containment, return or suspension of provision of products and services;
- informing the customer;
- obtaining authorization for acceptance under concession.

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

#### **8.7.2. Delta Systems retains documented information that:**

- describes the nonconformity;
- describes the actions taken;
- describes any concessions obtained;
- identifies the authority deciding the action in respect of the nonconformity.

REFERENCE: SOP-8.1.0.001 - Operational Planning and Control.doc  
REFERENCE: SOP-8.2.0.001 - Requirements for Products and Services  
REFERENCE: SOP-8.3.0.001 - Design and Development.docx  
REFERENCE: SOP-8.4.1.002 - Supplier Quality Manual.doc  
REFERENCE: SOP-8.4.2.001 - Incoming Inspection.docx  
REFERENCE: SOP-8.4.3.001 - Purchasing Information.docx  
REFERENCE: SOP-8.5.1.001 - Control of Production and Service Provision  
REFERENCE: SOP-8.5.2.001 - Identification and Traceability.docx  
REFERENCE: SOP-8.5.3.001 Property Belonging to Customers or External Providers.doc  
REFERENCE: SOP-8.5.4.001 - Preservation of Product.docx  
REFERENCE: SOP-8.6.0.001 Release of Products and Services.doc  
REFERENCE: SOP-8.7.1.001 Control of Nonconforming Output Product

## **9. Performance evaluation**

### **9.1. Monitoring, measurement, analysis and evaluation**

#### **9.1.1. General**

Delta Systems determines:

- what needs to be monitored and measured;
- the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;

when the monitoring and measuring are performed;

when the results from monitoring and measurement are analysed and evaluated.

Delta Systems evaluates the performance and the effectiveness of the quality management system.

Delta Systems retains appropriate documented information as evidence of the results.

### **9.1.2. Customer satisfaction**

Delta Systems monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. Delta Systems has determined the methods for obtaining, monitoring and reviewing this information.

Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

### **9.1.3. Analysis and evaluation**

Delta Systems analyses and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis are used to evaluate:

- conformity of products and services;
- the degree of customer satisfaction;
- the performance and effectiveness of the quality management system;
- if planning has been implemented effectively;
- the effectiveness of actions taken to address risks and opportunities;
- the performance of external providers;
- the need for improvements to the quality management system.

Methods to analyse data may include statistical techniques.

## **9.2. Internal audit**

### **9.2.1. Delta Systems conducts internal audits at planned intervals to provide information on whether the quality management system:**

conforms to:

- Delta Systems's own requirements for its quality management system;
- the requirements of the ISO 9001:2015 International Standard;

is effectively implemented and maintained.

#### **9.2.2. Delta Systems :**

plans, establishes, implements and maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which take into consideration the importance of the processes concerned, changes affecting Delta Systems, and the results of previous audits;

defines the audit criteria and scope for each audit;

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

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

takes appropriate correction and corrective actions without undue delay;

retains documented information as evidence of the implementation of the audit programme and the audit results.

### **9.3. Management review**

#### **9.3.1. General**

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

#### **9.3.2. Management review inputs**

Management reviews are planned and carried out taking into consideration:

the status of actions from previous management reviews;

changes in external and internal issues that are relevant to the quality management system;

information on the performance and effectiveness of the quality management system, including trends in:

customer satisfaction and feedback from relevant interested parties;

the extent to which quality objectives have been met;

process performance and conformity of products and services;

nonconformities and corrective actions;

monitoring and measurement results;

audit results;



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the performance of external providers;  
the adequacy of resources;  
the effectiveness of actions taken to address risks and opportunities (see 6.1);  
opportunities for improvement.

#### 9.3.3. Management review outputs

The outputs of the management review include decisions and actions related to:  
opportunities for improvement;  
any need for changes to the quality management system;  
resource needs.

Delta Systems retains this documented information as evidence of the results of management reviews.

REFERENCE: SOP-9.1.1.001 - Monitoring, Measurement, Analysis and Evaluation

REFERENCE: SOP-9.1.2.001 - Customer Satisfaction

REFERENCE: SOP-9.1.3.001 - Analysis and Evaluation

REFERENCE: SOP-9.2.2.001 - Internal Audits

REFERENCE: SOP-9.3.0.001 - Management Review

## 10. Improvement

### 10.1. General

Delta Systems determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

These include:

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

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

### 10.2. Nonconformity and corrective action

10.2.1. When a nonconformity occurs, including any arising from complaints, Delta Systems:

reacts to the nonconformity and, as applicable:

takes action to control and correct it;

deals with the consequences;

evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

reviewing and analysing the nonconformity;

determining the causes of the nonconformity;

determining if similar nonconformities exist, or could potentially occur;

implementing any action needed;

reviewing the effectiveness of any corrective action taken;

updating risks and opportunities determined during planning, if necessary;

makes changes to the quality management system, if necessary.

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

#### 10.2.2.

Delta Systems retains documented information as evidence of:

the nature of the nonconformities and any subsequent actions taken;

the results of any corrective action.

### 10.3. Continual improvement

Delta Systems continually improves the suitability, adequacy and effectiveness of the quality management system.

Delta Systems considers the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that need to be addressed as part of continual improvement.

REFERENCE: SOP-10.2.0.001 Corrective and Preventative Action (CAPA-CAR-PAR).docx

REFERENCE: SOP-10.3.0.001 Continual Improvement.docx