



Quality Management System Manual

**AS9100
ISO 9001
MIL-STD-790**

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QUALITY MANAGEMENT SYSTEM MANUAL APPROVALS

APPROVED BY: _____
Quality Manager

APPROVED BY: _____
General Manager

APPROVED BY: _____
Director of Operations

APPROVED BY: _____
Controller

APPROVED BY: _____
Engineering Manager

APPROVED BY: _____
Director of Sales & Marketing

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Quality Policy

SV Microwave is committed to achieving profitable growth by meeting our customer requirements with optimal technology solutions and continuous process improvement.

Quality Objectives;

- 10% Sales growth per year
- Profit to exceed rate of Sales growth
- Customer quality of shipped product to exceed 98% acceptance rate
- On Time Delivery to customer will exceed 90%

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0.2 Controlled Circulation

This Quality Management System Manual (“QM”) is the property of SV Microwave, Inc (“SV”).

Copies of this QM are available to our customers or government upon request.

The original of this manual is maintained by the Quality Manager, who is solely authorized to make changes to the manual. All revisions are recorded on the Amendment Record pages of this manual.

The QM is distributed and maintained on a controlled copy basis through PDF files on a secured network.

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The government representative and SV’s customers are notified, in writing, of all changes to the inspection system, when required by contractual obligation. Any changes recommended by the government/customer may be included into the system.

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0.3 Amendment Record

<u>REV.</u>	<u>DATE OF REVIEW</u>	<u>DATE OF REVISION</u>	<u>SECTIONS AFFECTED</u>	<u>REMARKS</u>	<u>EFFECTIVE DATE</u>
A-W				See records on file.	06/01/05
X	10/11/05	10/31/05	ALL	Part of restructuring of the Quality System documentation to a manageable 3 tier documentation system.	2/22/06
Y	05/04/06	07/16/06	Section 3.0 Section 7.0	Revised Organizational Chart Revised to include pertinent verbiage from AS9100	7/17/06
Z	08/01/06	01/19/07		DCN 34413	1/23/07
AA	03/07/08	03/14/08		DCN 35708	3/14/08
AB	04/23/08	05/05/08		DCN 35756	5/5/08
AC	09/17/08	09/17/08		DCN 36068	9/17/08
AD	05/01/09	05/01/09		DCN 36555	05/08/09
AE	03/01/10	03/01/10		DCN 37411	03/31/10
AF	03/11/11	03/11/11		DCN38080	03/31/11
AG	4/2/2012	4/2/2012		DCN38962	04/06/12
AH	05/21/12	05/21/12		DCN39088	05/21/12
AJ	07/31/13	07/31/13		DCN39900	07/31/13
AK	07/31/14	07/31/14	Section 3.0	DCN 40631	07/31/14
AL	03/19/15	03/31/15	Various	DCN 41244	03/31/15

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0.4 Acronyms

SV Microwave, Inc.	“SV”
Material Defect Report	“MDR”
Quality Management System Manual	“QM”
Quality Management System	“QMS”
Return Material Authorization	“RMA”
Standard Inspection Procedures	“SIP”
Standard Operating Procedures	“SOP”
Standard Test Procedures	“STP”
New Release Notice	“NRN”
Drawing Change Notice	“DCN”

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1.0 Process Effectiveness Approach

Process Effectiveness Assessments are performed on the areas identified as critical in developing, implementing and improving the effectiveness of the Quality Management System.

2.0 Scope and Exclusions

2.1 Quality Management System Scope

Design, development, manufacturing and testing of RF connectors and components.

2.2 Quality Management System Scope Exclusions

7.5.1.4 Post-Delivery Support

Justification: Reference section 7.5.1.4 for exclusion justification.

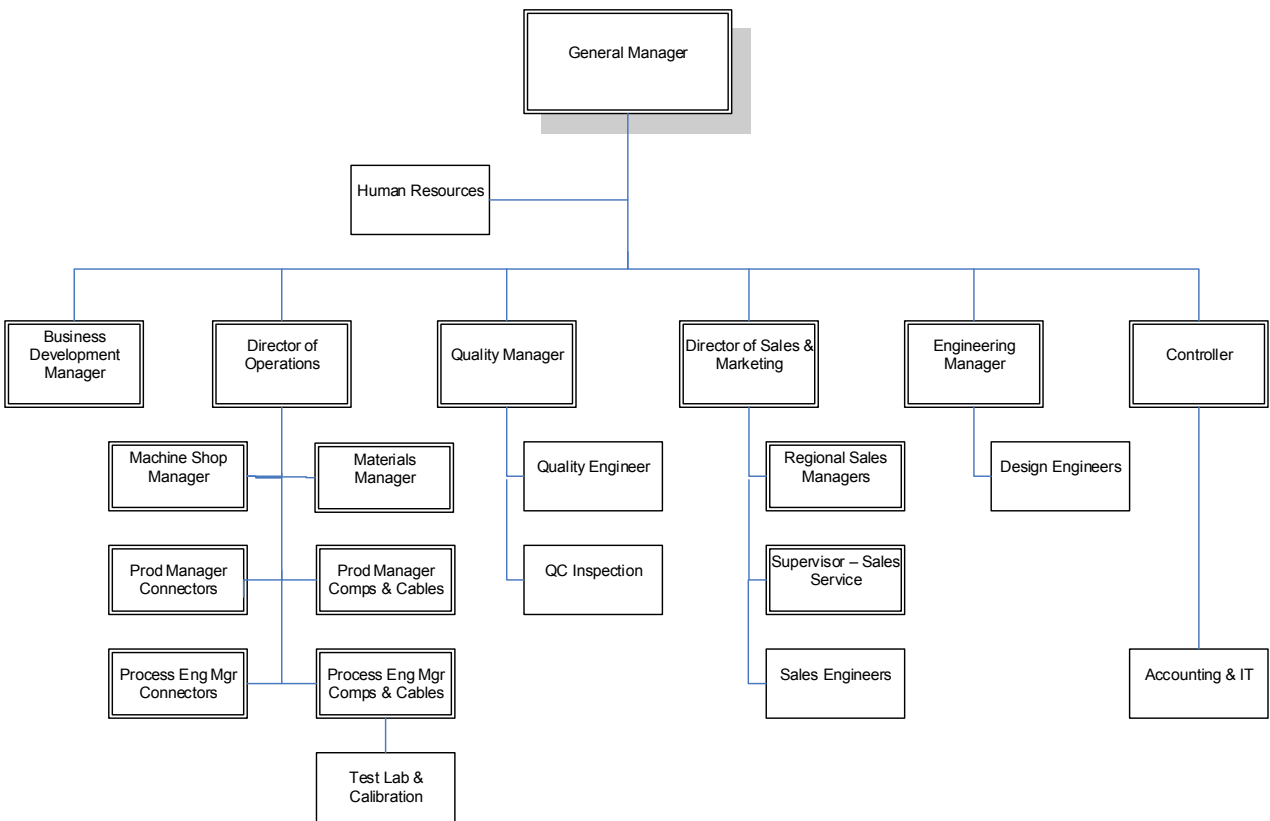
Not applicable per scope exclusion. SV does not provide post-delivery support for any product sold.

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3.0 Company Information

Figure 1

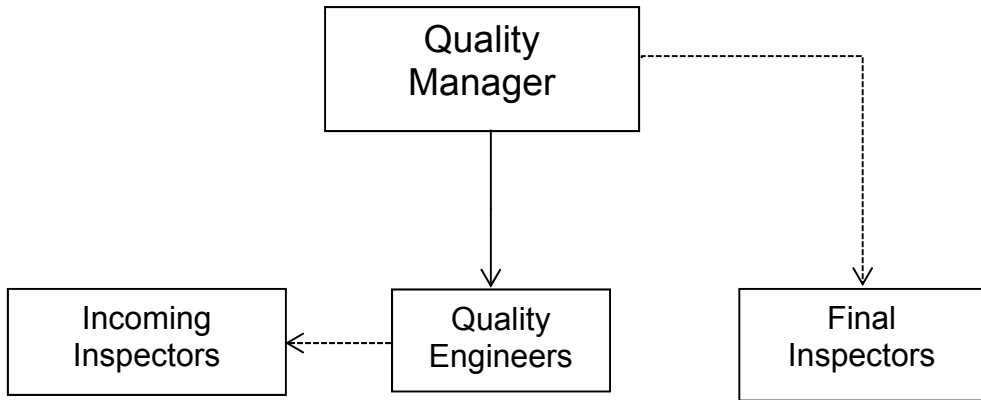
SV MICROWAVE, INC. ORGANIZATIONAL CHART



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Figure 2

**SV MICROWAVE, INC.
QUALITY ORGANIZATIONAL CHART**



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4.0 Quality Management System Requirements

Purpose

The quality management system described conforms to the requirements of ISO 9001 and AS9100 Section 4 — Quality Management System Requirements.

4.1 General Requirements (SOP Q4.1):

4.1.1 A quality management system has been established, documented, implemented, maintained and is continually improved in accordance with the requirements of AS9100 & ISO 9001. To implement the system, SV Microwave has:

- determined the processes needed for the quality management system and their application throughout the organization;
- determined the sequence and interaction of these processes;
- determined the criteria and methods needed to ensure that both the operation and control of these processes are effective;
- ensured the availability of resources and information necessary to support the operation and monitoring of these processes;
- defined processes to ensure control over outsourced activities and process
- monitored, measured (where applicable), and analyzed these processes; and,
- implemented actions necessary to achieve planned results and continual improvement of these processes.

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4.2 Documentation Requirements (SOP Q4.2):

4.2.1 General

SV's QMS documentation includes:

- a) documented statements of a quality policy and quality objectives
- b) Quality Manual
- c) Documented procedures and records required by ISO 9001 and AS 9100,
- d) Documents (including records) determined by SV to be necessary to ensure effective planning, operation and control of our processes,
- e) Quality system requirements imposed by the government and customer.

All SV people have access to QMS documentation and are aware of relevant procedures. Copies of these documents are made available to the government and/or customer representatives, upon request.

4.2.2 Quality Manual

SV has established and maintains a Quality Manual that includes:

- a) The scope of the QMS, including details and justification for any exclusion,
- b) Reference to the documented procedures established for the QMS, and
- c) A description of the interaction between the processes of the QMS.

At a minimum, SV's Quality Management Team reviews the entire QM, Quality Policy and Quality Objectives once a year.

4.2.3 Control of Documents

A documented procedure (SOP Q4.1) has been established to control SV's QMS documentation and defines the controls needed to:

- a) Approve documents for adequacy prior to issue,
- b) Review, update and re-approve documents, as necessary,
- c) Ensure that changes to documents and the current revision status are identified,
- d) Ensure that relevant versions of applicable documents are available at all points of use

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- e) Ensure that documents remain legible and readily identifiable,
- f) Ensure that documents of external origin determined by SV to be necessary for the planning and operation of the QMS are identified and their distribution is controlled, and
- g) Prevent the unintended use of obsolete documents, and to apply suitable identification to them, if they are retained for any purpose.

SV coordinates document changes with customers and/or regulatory authorities in accordance with contract or government requirements.

4.2.4 Control of Records (SOP Q4.2.1)

SV establishes and maintains control of records to provide evidence of conformity to requirements and of the effective operation of the QMS. Records are handled per the published Document Control procedure with regard to identification, storage, protection, retrieval, retention and disposition of records to ensure that they remain legible, readily identifiable and retrievable.

SV establishes documents and maintains the method of controlling records that are created by and/or retained by suppliers.

All records are available for review by customer and regulatory authorities.

5.0 Management Responsibility (SOP Q5.0)

Scope and Purpose

The quality system described in this section of the QM conforms to the requirements of the standard: Section 5 — Management Responsibility. This policy defines the company commitment to quality.

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5.1 Management Commitment

Top management has provided evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements;
- establishing the quality policy;
- ensuring that quality objectives are established;
- conducting management reviews; and,
- ensuring the availability of resources.

5.2 Customer Focus

Top management has ensured that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction.

Top management has ensured that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not , or will not be, achieved.

5.3 Quality Policy

Top management has ensured the quality policy is:

- appropriate to the purpose of the organization;
- includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system;
- provides a framework for establishing and reviewing quality objectives;
- communicated and understood within the organization; and,
- reviewed for continuing suitability.

See Section 1.0 for Quality Policy.

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5.4 Planning and Quality Objectives

Top Management has ensured quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy.

5.4.1 Quality Management System Objectives

Top Management has ensured that:

- the planning of the quality management system is carried out to meet the general requirements of this international standard (section 4.1); and,
- the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

- The responsibilities and authorities are defined and communicated within the organization through the Quality Manual, Standard Operating Procedures, Organizational Charts, Position Profiles and Training. The Quality Management Plan is used as a supplement.
- All defined authorities are delegated from the approvers to the process owners of this manual.

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5.5.2 Management Representative

The Quality Management Team has appointed the Director of Operations as the Management Representative with responsibilities and authorities that:

- Ensures that processes needed for the QMS are established, implemented and maintained,
- Reports to the Quality Management Team on the performance of the QMS and any need for improvement,
- Ensures the promotion of awareness of customer requirements throughout the organization,

Has the organizational freedom and unrestricted access to top management to resolve quality management issues.

5.5.3 Internal Communication

Senior Management has ensured appropriate communication processes are established within the organization and the communication takes place regarding the effectiveness of the quality management system.

5.6 Management Review

The Quality Management Team reviews the SV QMS on an annual basis, at a minimum, to ensure its continuing suitability, adequacy, efficiency and effectiveness. The review includes assessing opportunities for improvement and the need for changes to the QMS, including the Quality Policy and Quality Objectives.

Records from Management Reviews are developed and maintained by the Management Representative.

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The input to Management Review includes information on:

- a) Results of audits,
- b) Customer feedback,
- c) Process performance and product conformity,
- d) Status of preventive and corrective actions,
- e) Follow-up actions from previous Management Reviews,
- f) Changes that could affect the QMS, and
- g) Recommendations for improvement.
- h) A review of the quality policy and objectives
- i) A review of the risk and mitigation

The output from the Management Review includes any decisions and actions related to:

- a) Improvement of the efficiency and effectiveness of the QMS and its processes,
- b) Improvement of product related to customer requirements, and
- c) Resource needs.

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6.0 Resource Management (SOP Q6.0)

Scope and Purpose

The quality system described in this section of the QM conforms to the requirements of the standard: Section 6 — Resource Management.

6.1 Provision of Resources

SV Microwave has determined and provided resources needed to implement and maintain the QMS and continually improve its effectiveness, and to enhance customer satisfaction by meeting customer requirements.

6.2 Human Resources

Processes are in place to monitor and maintain the competency of the workers who affect conformity to product requirements with respect to education, training, skills and experience. This includes persons who indirectly may affect conformity to product requirements. Position Profiles are used which contain relevant information on required training, education and other qualifications that may be a pre-requisite for the applicable position.

New employees are screened through a comprehensive interview process prior to being hired. Tools such as the PI (Predictive Index) and Wonderlic are given to applicants based on job profile requirements. Prior experience, relevant training and/or formal education are factors considered during the interview process. When required, SV provides training, or other necessary actions to ensure employee competence and awareness.

6.3 Infrastructure

The required infrastructure needed to achieve conformity to product requirements is continually reviewed and maintained. Infrastructure includes, as applicable;

- a) Buildings, workspace and associated utilities,
- b) Process equipment (both hardware and software), and
- c) Supporting services (such as transport, communication or information systems).

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6.4 Work Environment

The work environment, including temperature, humidity, lighting, noise, weather, cleanliness, protection from electrostatic discharge, and safety is continually monitored and maintained to achieve conformity to product requirements. Environmental, Health & Safety requirements are outlined in the SV Microwave Contingency Plan (OCP 001).

7.0 Product Realization

Scope and Purpose

The quality system described in this section of the QM conforms to the requirements of the standard: Section 7 — Product Realization.

7.1 Product Realization (SOP Q7.1)

The processes needed for product realization are planned and developed, and are consistent with the requirements of the other processes of the quality management system. In planning product realization, the following has been determined, as appropriate:

- quality objectives and requirements for the product;
- the need to establish processed documents, and to provide resources specific to the product;
- required verification, validation, monitoring/measurement, inspection and test activities specific to the product and the criteria for product acceptance;
- records needed to provide evidence that the realization processes and resulting product meet requirements; and,
- configuration management appropriate to the product
- planning output is in a suitable form for methods of operation.
- the identification of resources to support the use and maintenance of the product.

7.1.1 Project Management

Management assigns responsibility for project management and ensuring that product realization is planned and managed in a controlled manner, meeting requirements at acceptable risk, within resource and schedule constraints.

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7.1.2 Risk Management

Risks are managed according to the Risk Management procedure. The process of risk management includes;

- Assigning responsibility for risk management
- Defining risk criteria
- Identification, assessment and communication of risks
- Identification, implementation and management of actions to mitigate risks
- Acceptance of risks remaining after implementation of mitigating actions

7.1.3 Configuration Management

SV establishes implements and maintains a configuration management process that includes as appropriate to the product.

- Configuration management planning
- Configuration identification
- Change control
- Configuration status accounting and
- Configuration audit

7.1.4 Control of Work Transfers

Temporary or permanent transfer of work is planned to control and verify the conformity of the work to requirements. Planning takes place according to the Planning of Realization Processes procedure.

7.2 Customer Related Processes (SOP Q7.2)

7.2.1 Determination of Requirements Related to the Product:

7.2.1.1 Requirements related to the product have been determined, including:

- requirements specified by the customer, including the requirements for delivery;
- requirements not stated by the customer but necessary for specified or intended use, where known;
- statutory and regulatory requirements applicable to the product; and,
- determination of any additional requirements, including post delivery, considered necessary by SV.

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7.2.2 Review of Requirements Related to the Product

Requirements related to the product are reviewed. This review is conducted prior to committing to supply a product to customers, and ensures that:

- a) Product requirements are defined,
- b) Contract or order requirements differing from those previously expressed are resolved,
- b) SV has the ability to meet the defined requirements,
- c) special requirements of the product are determined
- d) Records of the results of review and actions arising from the review are maintained, and
- e) Risks (e.g. such as new technology, short delivery time frame, etc.) have been identified.

Where the customer provides no documented statement of requirement, SV's Sales and Marketing Department confirms the customer requirements before acceptance.

Where product requirements are changed, SV ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Customer Communication

Effective arrangements are determined and implemented for communicating with customers in relation to:

- a) Product information,
- b) Inquiries, contracts or order handling, including amendments, and
- c) Customer feedback, including customer complaints.

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7.3 Design and Development (SOP Q7.3)

7.3.1 Design and Development Planning

The product design and development is planned and controlled. Processes and procedures are established to ensure, during the design and development process, that the following are reviewed:

- a) Design and development stages, including process flow,
- b) Review, verification and validation that are appropriate to each design and development stage, and
- c) Responsibilities and authorities for design and development.

Where appropriate, , the design effort is divided into the design and development efforts as distinct activities and for each activity define the task, necessary resources, responsibilities, design content, input and output data and the planning constraints.

Design and development tasks to be carried out are defined based on the specified safety/regulatory or functional objectives of the product in accordance with customer, statutory and regulatory authority requirements.

The interfaces between the various design elements involved to ensure effective communication and clear assignment of responsibility are managed.

Planning output is updated, as appropriate, as the design and development progresses.

7.3.2 Design and Development Inputs

Inputs relating to product requirements are determined and records maintained. The design inputs include, as appropriate:

- a) Functional and performance requirements,
- b) Applicable government requirements,
- c) Where applicable, information derived from previous similar designs, and
- d) Other requirements essential for design and development.

Inputs are reviewed for adequacy. All requirements are verified to be complete, unambiguous and not in conflict with each other.

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7.3.3 Design and Development Outputs

Design outputs are in a form suitable for verification and are reviewed and approved, prior to release, to enable verification against the design and development inputs.

Design and development outputs:

- a) Meet the input requirements for design and development,
- b) Provide appropriate information for purchasing, production and service provision,
- c) Contain or reference product acceptance criteria,
- d) Specify the characteristics of the product that are essential for its safe and proper use and storage, and
- e) specify as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items.

Pertinent data and documentation which allow the product to be identified, manufactured, inspected, used and maintained are defined. Examples include:

- A list of the drawings, part lists and specifications necessary to define the configuration and the design features of the product, and
- Information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product.

7.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development are performed in accordance with planned arrangements to:

- a) Evaluate the ability of the results of design and development to meet requirements,
- b) Identify any problems and propose necessary actions, and
- c) Authorize progression to the next stage.

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7.3.5 Design Review and Development Verification

Verification of design and development is performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions are maintained.

7.3.6 Design and Development Validation

Validation of design and development is performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained.

7.3.6.1 Documentation of Design and Development Verification and Validation

Where tests are necessary for verification and validation, these tests are planned, controlled, reviewed and documented to ensure and prove the following:

- a) Test plans or specifications identify the product being tested and the resources being used; and define test objectives and conditions, parameters to be recorded and relevant acceptance criteria,
- b) Test procedures describe the method of operation, the performance of the test and the recording of the results,
- c) The correct configuration standard of the product is submitted for the test,
- d) The requirements of the test plan and the test procedures are observed, and
- e) The acceptance criteria are met.

7.3.6.2 Design and Development Verification and Validation testing

At the completion of design and development, the Design Review Team reviews reports, calculations and test results to demonstrate that the product definition meets the specification requirements for all identified operational conditions.

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7.3.7 Control of Design and Development Changes

Design and development changes are identified and records maintained. The changes are controlled in accordance with the configuration management process. The evaluation of the effect of the changes on constituent parts and product already delivered is conducted and the record of the result of the evaluation is maintained.

The design and development change documents are available, upon request, for customer and/or government authority review. When required by contract or regulatory requirements, the design and development change control process is provided for customer and/or regulatory authority approval of changes.

As required by customers, based on design types, prototype parts for change evaluation are produced under controlled conditions.

7.4 Purchasing (SOP Q7.4)

7.4.1 Purchasing Process

Purchasing processes are controlled to ensure purchased product conforms to specified purchase requirements. The type and extent of control is applied to suppliers and purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

SV is responsible for the for the conformity of all products purchased from suppliers, including product from sources defined by the customer.

Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements. Criteria for selection, evaluation and re-evaluation and any necessary actions arising from the evaluation are maintained, per the following.

- a. a register of approved suppliers that includes the approval status and the scope of the approval is maintained;
- b. periodically reviewing supplier performance; records of these reviews are used as a basis for establishing the level of controls to be implemented;

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- c. defining the necessary actions to take when dealing with suppliers that do not meet requirements;
- d. ensuring where required that both SV and all suppliers use customer approved special process sources;
- e. define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on their approval status and
- f. determine and manage the risk when selecting and using the suppliers

7.4.2 Purchasing Information

Purchasing information describes the product to be purchased, including where appropriate:

- a) Requirements for approval of product, procedures, processes and equipment,
- b) Requirements for qualification of personnel,
- c) QMS requirements,
- d) The name and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data,
- e) The identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data,
- f) Requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by the organization, and as applicable critical items including key characteristics,
- g) Requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing,

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- h) Requirements regarding the need for the supplier to
- i) Notify the organization of nonconforming product,
- j) Obtain organization approval for nonconforming product disposition,
- k) Notify the organization of changes in product and/or process, changes of suppliers, change of manufacturing facility location and, where required, obtain organization approval, and
- l) Flow down to the supply chain the applicable requirements including customer requirements,
- m) Records retention requirements, and,
- n) Right of access by the organization, their customer and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records.

The adequacy of specified purchase requirements prior to their communication to the supplier is verified.

The guidelines for the levels of authority for all purchases are defined.

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7.4.3 Verification of Purchased Product

A verification process has been implemented to ensure that purchased product meets specified purchased requirements.

Verification activities include, as appropriate:

- a) Obtaining objective evidence of the quality of the product from the suppliers.
 - It is not SV’s standard policy to perform (or authorize suppliers to perform) verification of product conformance at the supplier’s facility. If performed, this verification does not replace SV’s Incoming Inspection, nor absolve the supplier for submitting conforming product.

- b) All incoming products and services (brazing, plating, heat treat, annealing, etc.) are inspected by the supplier at their premises and verified by SV’s Incoming Inspection personnel prior to acceptance.
 - On-site audits (supplier site) are performed where determined necessary.
 - Where specified in the contract, the customer or the customer’s representative shall be afforded the right to verify at the supplier’s premises and SV’s premises that subcontracted product conform to specified requirements.
 - Verification by the customer will not be used by SV as evidence of effective control of quality by the supplier and shall not absolve the organization of the responsibility to provide acceptable produce, nor shall it preclude subsequent rejection by the customer.

- c) Review of the required documentation
 - Where SV utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. SV periodically validates test reports for raw material.

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- b) Inspection of products upon receipt. No purchased product is released from Incoming Inspection until it has been verified as conforming to specified requirements, unless it is released under positive recall procedure.
- c) A supplier certification/Dock-to-Stock program is continuously targeted, enabling elimination of inspection activity at SV incoming.
- d) Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.

7.5 Production Provision (SOP Q7.5)

7.5.1 Control of Production

During production planning, the following are always considered:

- The establishment of process control and development of control plans,
- The identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of product realization,
- The design, manufacture and use of tooling so that variable measurements can be taken, and
- Special processes

The following controlled conditions are in place prior to production of a customer order:

- a) Availability of information that describes the characteristics of the product,
- b) Availability of work instructions, as necessary,
- c) Use of suitable equipment,
- d) Availability and use of monitoring and measuring equipment,
- e) Implementation of monitoring and measurement,
- f) Implementation of product release and delivery,
- g) Accountability for all products during manufacture (e.g., part quantities, split orders, nonconforming product),

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- h) Evidence that all manufacturing and inspection operations are completed as planned, or as otherwise documented and authorized,
- i) Provisions for prevention, detection and removal of foreign objects,
- j) Monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality, and
- k) Criteria of workmanship.

7.5.1.1 Production process verification

The following data is in place prior to production of a customer order:

- a) Drawings, part lists, production and inspection steps and documents, and
- b) Lists of specific or non-specific tools required and any specific instruction associated with their use.

SV uses 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 capable of producing parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

7.5.1.2 Control of Production Process Changes

SV has identified the person authorized to approve changes to production processes.

Changes that affect processes, production equipment, tools and programs are controlled and documented, by manufacturing engineering, quality, etc.

As required by contract or government requirements, SV identifies and obtains acceptance of changes that require customer and/or government approval.

Results are assessed of changes to production processes to confirm that the desired effect is achieved without adverse effects to product quality.

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7.5.1.3 Control of Production Equipment, Tools and Software Programs

Production equipment, tools and programs are validated through first sample runs prior to use. These are maintained and inspected periodically according to procedure requirements. As required by customers or the government, validation prior to production may include verification of the first article produced to the design.

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

Production equipment is located in the work center area. Tools are stored in protected storage. Equipment is checked for its condition prior to use. Assembly tooling is checked at first-four inspection at the start of an operation.

7.5.1.4 Control of Service Operation

Not applicable per scope exclusion. SV does not service any product sold.

7.5.2 Validation of Processes for Production

Processes for production and service where the resulting output cannot be verified by subsequent monitoring or measurement and as a consequence deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results. Arrangements are established for these processes including, as applicable:

- a) Defined criteria for review and approval of the processes, equipment and qualification of personnel,
- b) Qualification and approval of special processes prior to use, including approval of equipment and qualification of personnel
- c) Use of specific methods and procedures, including control of significant operations and parameters of special processes in accordance with documented process specifications,
- d) Requirements for records, and
- e) Revalidation.

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7.5.3 Identification and Traceability

Product is identified, where appropriate, by suitable means throughout production realization.

The identification of the configuration of the product will be maintained in order to identify any differences between the actual configuration and the agreed configuration.

The status of the product is identified with respect to measurement and monitoring requirements throughout the realization. Where traceability is a requirement, the unique identification of product is controlled and records are maintained.

- a) When acceptance authority media are used (e.g. stamps, electronic signatures, passwords), SV has established and documented controls for the media.
- b) At no time will signature stamps be used by anyone other than the person whose name is on the stamp.

7.5.3.1 According to the level of traceability required by contract, regulatory or other established requirements, SV ensures that the traceability:

- a) Is maintained throughout the date required by the contract,
- b) Of the products manufactured from the same batch of raw material or from the same manufacturing batch, as well as the destination (delivery, scrap) of all products from the same batch is maintained,
- c) For an assembly, the identity of its components and those of the next higher assembly is available and maintained, and
- d) Includes a sequential record of the production (e.g. manufacture, assembly, inspection) is available and easily retrievable.

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7.5.4 Customer Property

SV exercises care with all customer property including intellectual property and personal data (e.g. customer furnished data used for design, production and/or inspection) while it is under SV's control or being used by SV.

Customer property provided for use into the product is identified, verified, protected and safeguarded. If any customer property is lost, damaged or otherwise found to be unsuitable for use, it is reported to the customer and records are maintained.

7.5.5 Preservation of Product

The integrity, with regards to maintaining conformity, of product is maintained during internal processing and delivery to the intended destination. This includes identification, handling, packaging, storage and protection.

All SV people ensure that all material is handled with the utmost care to prevent any possible damage.

Where applicable, preservation of products includes provisions for:

- a) Cleaning,
- b) Prevention of damage, detection and removal of foreign objects,
- c) Special handling for sensitive products,
- d) Marking and labeling, including safety warning,
- e) Shelf life control and stock rotation, and
- f) Special hazardous materials.

SV ensures that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.

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7.6 Control of Monitoring and Measuring Equipment (SOP Q7.6)

All gauges and measuring and test equipment used to assure that products conform to pre-determined requirements are listed on a master list and are maintained through an established calibration system. The calibration system includes details of equipment type, unique identification, location, frequency of checks, verification method and acceptance criteria.

The calibration system is periodically audited and reviewed for adequacy.

Monitoring and measurement equipment include, as applicable, but are not limited to: test hardware, test software, automated test equipment (ATE) and employee owned and customer supplied equipment used to provide evidence of product conformity.

The calibration system ensures that monitoring and measurement are carried out under suitable environmental conditions, in a manner that is consistent with the monitoring and measurement requirements.

To ensure valid results, measuring equipment is:

- a) Calibrated or verified (or both) against measurement standards per BS/EN ISO/IEC 17025, ANSI Z540.3 and/or MIL-STD-45662A* prior to use and at specified intervals based on usage. Records of the results of all calibration and verification are maintained,
- b) Adjusted and re-adjusted as necessary,
- c) Identified to enable the calibration status to be determined. Labels are affixed to all calibrated test equipment and inspection tools. Each label denotes the date of calibration, due date for next calibration and the name or initials of the person who conducted the calibration, as minimum,
- d) Safeguarded from adjustments that would invalidate the measurement results, where applicable.
- e) Handled with the utmost care to protect it from damage and deterioration during use, maintenance and storage. Spare and unused equipment is stored under controlled conditions. If any instance of improper handling or storage of calibration equipment occurs, the Quality Assurance Manager is notified immediately and, in cases where gross neglect is evident, a corrective action investigation is conducted, and

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f) Recalled to a defined method when requiring calibration.

*MIL-STD-45662A is an obsolete military specification that is still referenced and required by some customers.

The validity of the previous measuring results is assessed and recorded when the equipment is found not to conform to requirements. Appropriate action is taken on the equipment and any product affected. Records of the results of calibration and verification are maintained and are available for review or inspection.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy intended application is confirmed prior to initial use and reconfirmed as necessary.

Measuring and test standards, as well as the personnel who operate the equipment, are available to customer and/or government contractors, as required.

8.0 Measurement, Analysis and Improvement

Scope and Purpose

The quality system described in this section of the QM conforms to the requirements of the standard: Section 8 — Measurement, Analysis and Improvement.

8.1 General

A system has been implemented for monitoring, measurement, analysis and improvement processes needed, to:

- a) Demonstrate conformity of the product to requirements,
- b) Ensure conformity of the QMS, and
- c) Continuously improve the effectiveness of the QMS.

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This includes determination of applicable methods, including statistical techniques, and the extent of their uses.

This system is continuously reviewed for improvement opportunities.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction (SOP Q8.1)

The customer satisfaction evaluation process is established, which includes methods to obtain, monitor and utilize information relating to customer perception as to whether SV meets the customer’s requirements.

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

8.2.2 Internal Audit (SOP Q8.2)

A documented internal audit procedure has been established, planned and implemented to determine whether the QMS:

- a) Conforms to the planned arrangements to the requirements of ISO 9001, AS9100 and MIL-STD-790,
- b) Conforms to requirements as required by the customer and/or government, and
- c) Is maintained and implemented effectively.
- d) Can be improved.

The audit criteria, scope, frequency and methods are determined and reviewed based on the status and importance of the processes and the areas to be audited. As applicable, SV employs tools and techniques such as check sheets, process flowchart, or any similar methods to support the QMS audit and improve its effectiveness. These tools are revised and modified as needed based on the results of audits to ensure overall QMS effectiveness.

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Internal auditors are scheduled to ensure that they are independent of the areas they are auditing.

Results of audits are documented and maintained. Results are reviewed minimum quarterly at management review meetings.

Corrective actions are required for any findings of non-compliance. The responsible management representative for the area with the non-compliance reviews all findings and establishes the root cause of non-compliance, method to correct the existing condition, and the preventive action instituted to prevent the non-compliance from recurrence, are taken without undue delay.

Follow-up activities include the verification of the actions taken and the reporting of verification results, as appropriate.

8.2.3 Monitoring and Measurement of Processes

Processes are monitored, measured and the results are reviewed to ensure achievement of planned results. The suitability of measurements and measurement methods are reviewed during Management Reviews. When planned results are not achieved, the necessary connective and preventive actions are taken without undue delay.

- a) To take appropriate action to correct the nonconforming process,
- b) To evaluate whether the process nonconformity has resulted in product nonconformity,
- c) To determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and
- d) To identify and control any nonconforming product (see 8.3).

The effectiveness of SV’s QMS is monitored and measured through the internal audit program.

When specified in the individual customer specification, a statistical process control (SPC) program system in accordance with ANSI/EIA-557-B-2006 is established.

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8.2.4 Monitoring and Measurement of Products

The characteristics of the product are monitored and measured to verify that product requirements are fulfilled. This is completed at appropriate stages of the product realization process in accordance with planned arrangements.

Measurement requirements for product acceptance are documented and include;

- a) criteria for acceptance and/or rejection,
- b) where in the sequence measurement and testing operations are performed,
- c) required records of the measurement results (at a minimum, indication of acceptance or rejection), and
- d) any specific measurement instruments required and any specific instructions associated with their use

When critical items, including key characteristics, have been identified the SV will ensure they are controlled and monitored in accordance with the established processes.

When sampling inspection as a means of product acceptance is used, the sampling plan shall be 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.

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

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing the release of product.

Where required to demonstrate product qualification, records will provide evidence that the product meets the defined requirements.

Product release and service delivery to the customer do not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable, by the customer. All records authorizing release of product for delivery indicate the responsible person.

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8.2.4.1 **Inspection Documentation:** Measurement requirements for product acceptance is documented, including criteria for acceptance/rejection; where in the sequence of the process does the measurement take place; requirements for record retention; and instructions for taking the measurement.

8.2.4.2 **First Article Inspection:** A process is established for the verification and documentation of a representative sample of the first production run of a new part or following any significant change to the process/design of that part.

8.3 Control of Nonconforming Product (SOP Q8.4)

Product that does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in a documented procedure.

Where applicable nonconforming product is dealt with by one or more of the following manners:

- ◆ by taking action to eliminate the detected nonconformity;
- ◆ by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; and,
- ◆ by taking action to preclude its original intended use or application,
- ◆ by taking action appropriate to the effect (or potential effects) when nonconformity product is detected after delivery has begun.
- ◆ by taking actions necessary to contain the effect of the nonconformity on other processes or products

Unless specifically authorized by the customer, dispositions of use-as-is or repair will not be granted on the product specially produced to customer design, or if the non-conformity results in a departure from the contract requirements.

Product dispositioned for scrap is positively controlled, until physically rendered unusable.

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8.4 Analysis of Data (SOP Q8.5)

Appropriate data which demonstrates the suitability and effectiveness of the QMS system is collected and analyzed for opportunities for continuous improvement. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

- a) Customer satisfaction,
- b) Conformity to product requirements,
- c) Characteristics and trends of processes and products including opportunities for preventive action, and
- d) Supplier performance.

8.5 Improvement

8.5.1 Continual Improvement (SOP Q8.6)

Improvement of the effectiveness of the QMS is performed through the use of the Quality Policy, Quality Objectives, audit results, analysis of data, corrective and preventive actions, Management Reviews, and training in alternative methods in design and operations.

SV monitors the implementation of improvement activities and evaluates the effectiveness of the results.

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8.5.2 Corrective Action (SOP Q8.7)

Causes of non-conformities are determined and eliminated in order to prevent recurrence. Corrective actions are appropriate to the effects of the non-conformities encountered.

The corrective action system is directed at product/process deficiencies where failures or defects are greater than the prescribed limit.

A procedure for corrective action is established to:

- a) Reviewing non-conformities,
- b) Determining the root cause of non-conformities,
- c) Evaluating the need for action to ensure that non-conformities do not recur,
- d) Determining and implementing action needed,
- e) Identifying and maintaining records of results of action taken,
- f) Reviewing the effectiveness of the corrective action taken,
- g) Flowing down corrective action requirements to a supplier, when it is determined that the supplier is responsible for the root cause, and
- h) Identifying specific actions where timely and/or effective corrective actions are not achieved.
- i) Determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required

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8.5.3 Preventive Action (SOP Q8.7)

In order to determine action(s) to eliminate the causes of potential non-conformities and/or to prevent their occurrences, a procedure for preventive action is established to:

- a) Determine potential non-conformities and their causes,
- b) Evaluate the need for action to prevent occurrence of similar future non-conformities,
- c) Determine and implement action needed,
- d) Identify and maintain records of results of action taken, and
- e) Review the effectiveness of the preventive actions taken and ensure that they are appropriate to the effects of the potential problem(s)
- f) Review potential improvements.

8.5.4 Failure Analysis (SOP Q8.7)

When failures exceeding the number allowed by the specification are determined to be systemic, or as otherwise required by customer, the Engineering Department performs failure analysis.

9.0 MIL-STD-790 Requirements

9.1. Test Facilities

All test facilities, and any equipment used for qualification and/or conformance testing, are identified. These are documented on the individual test packages delivered with the samples.

9.2 GIDEP Alerts

The appropriate qualifying activity is notified of all pending GIDEP alerts prior to their issuance.

9.3 Sub-assembly Facilities

Sub-assembly facilities are not utilized without prior approval of the appropriate qualifying activity in accordance with the authorized qualification system.

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9.4 Distributors

Only Class A Distributors are selected and authorized to store, pack, handle and distribute our QPL products.

All Class A Distributors are audited to ensure that they meet the requirements of MIL-STD-790.

10.0 Reference Documents

The QM is in accordance with the following documents:

- MIL-I-45208 “Inspection System Requirements”*,
- MIL-STD-790 “Standard Practice for Established Reliability and High Reliability Qualified Products (QPL) Systems for Electrical, Electronic, and Fiber Optic Parts Specification”,
- ANSI/ASQ Z1.4-2008 “Sampling Procedures and Tables for Inspection by Attributes”,
- MIL-STD-45662 “Calibration System Requirements”*,
- ANSI Z540.3 - 2006, “Requirements for the Calibration of Measuring/Test Equipment”,
- BS/EN ISO/IEC 17025-2005, “General Requirements for the Competence of Testing and Calibration Laboratories”,
- ISO 9001 “Quality Management Systems – Requirements”,
- ISO 9004 “Quality Management Systems - Guidelines for Performance Improvements”,
- SAE AS9100 “International Aerospace Standard for Quality Systems Model for Quality Assurance in Design, Development, Production, Installation, and Servicing”, and
- AMS/EIA-557-B-2006 “Statistical Process Control Systems”.

*MIL-I-45208 and MIL-STD-45662 are obsolete military specifications that are still referenced and required by some customers.

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