



QUALITY POLICY MANUAL

SOLITRON DEVICES, INC.

QUALITY POLICY MANUAL

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REV.	DATE	SECTION CHANGED	AUTHORIZATION
A	10/25/99	All-Initial release	RFCH5991
B	01/14/00	Page 7 Quality Policy statement 4.1.3 review meeting frequency	RFCH6076
C	01/28/00	Page 7 Quality Policy statement	RFCH6089
D	04/13/00	Page 9 Management Responsibility	RFCH6203
E	08/22/00	All-Added revision history & distribution index. Changed Introduction to Rev. C 4.1 to Rev. C	RFCH7051
F	11/19/01	Page 1 of 37 Executive Staff Organization Chart	RFCH7051
G	12/20/01	Management Responsibility	RFCH7091
H	02/25/02	Management Responsibility 4.1 Engineering Manager & Purchasing Manager	RFCH7189
I	10/10/02	Added/RMA was not referenced on Section 4.19	RFCH7453
J	06/03/03	QPM01 Quality Policy Manual re-written to comply with ISO9001:2000	RFCH7692
K	09/18/03	QPM01 Quality Policy Manual re-written to comply with ISO9001:2000 Added Para 4.1 Flow Charts for Continual Improvement of the QMS System Process & their interaction	RFCH7869
L	06/02/04	Changes to Distribution List Index page 5 and to Para 1.0 Introduction deleted "and with over 100 employees today" page 6 per ISO Audit request.	RFCH8162
M	04/06/05	Deleted last sentence in Para 5.1 "The interrelation of personnel who manage, perform and verify work affecting quality is defined on the organization chart on Page 14" Reason of change for clarification.	RFCH8426
N	07/07/05	Replaced Executive Organization Chart with an updated.	RFCH8495
P	07/18/06	Changes for clarification on pages 14,19,21,29,and 33	RFCH8887
R	10/06/08	Update to AS9100 quality system	RFCH9482
S	12/22/08	Update to ISO9001:2008	RFCH9584
T	06/01/09	Update to comply with AS9100	RFCH9718
U	07/13/09	Update to comply with AS9100 Audit	RFCH9755
V	10/05/09	Replace 5.6.1 General with text below as per AS9100	RFCH9843
W	06/15/11	Review and revise to AS9100C	RFCH10461
X	06/16/11	Removed last two paragraphs on Page 29	RFCH10512
Y	09/09/11	Modified section 1.2 Application on page 6	RFCH10589

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DISTRIBUTION LIST

BOOK NUMBER	LOCATION
1	President/CEO
2	QA Manager
3	Finance Director
4	Sales/Marketing
5	Engineering
6	QA Engineer
7	Purchasing
8	Machine Shop
9	TDE
10	Hybrid Production
11	Audit Team (A)
12	Data Review
13	Audit Team (B)
14	Document Control
15	Production Control
16	Discrete Test
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18	Environmental

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1. SCOPE

1.1. General

Solitron Devices, Inc., a public company based in West Palm Beach, FL., Designs, Develops and Manufactures High Quality, High Reliability Power Semiconductors and Hybrids. Established in 1959, Solitron Devices, Inc. is a recognized Leader and Pioneer in the Innovative Design and Manufacturing of State-of-the Art Power Semiconductor products. Solitron Devices, Inc. is well known for producing custom and standard power solid-state components for the Aerospace, Defense, Industrial, Medical, and Commercial Industries. Solitron Devices, Inc.'s advanced semiconductor device and packaging technology has contributed to the success of virtually every U.S. and European Aerospace and Defense program.

Solitron Devices, Inc. pioneered the combining of small signal circuitry with power semiconductors to create hybrid circuits for high-end industrial, aviation, space and defense applications. Our unique capability as a vertically integrated semiconductor manufacturer providing its own in-house fabrication of semiconductor die, printed substrates and packages is a major cost and time saving benefit for our customers.

Solitron Devices, Inc. has a firm commitment to Quality and Excellence as well as strict adherence to the stringent requirements of Industrial, Aviation, Space and Defense Specifications. Solitron Devices, Inc. supports its products and services with a comprehensive Service/Quality program that is second to none.

We achieve this through:

- A management philosophy of Continual Improvement in all aspects of company performance.
- Well engineered and validated new product design processes.
- Vendor selection process based on long term relationships.
- Responsive assistance to customers, with on-site support when needed.

Solitron Devices, Inc. has implemented a Quality Management System that complies with AS9100/ ISO9001 to better satisfy the needs of our Customers.

1.2. Application

Solitron Devices, Inc. has determined that the following requirements are not applicable to the operations and are documented as exclusions:

- Section 7.3.6 Design and Development Validation; 7.3.6.1 Design and Development Verification and Validation Testing; 7.3.6.2 Design and Development Verification and Validation Documentation.
Justification: Our Customer normally does design validation of our product, however, where the contract specifies, we can support our Customer's effort where possible.
- Service Provision sections 7.5.1.4 a, c, d, e.
Justification: Solitron Devices, Inc. does not provide Service.

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2. APPLICABILITY

This Quality Manual covers the five major clauses of AS9100/ISO9001.

- Quality Management System
- Management Responsibility
- Resource Management
- Product Realization
- Measurement, Analysis, and Improvement

Each clause consists of elements followed by a policy statement defining the principles and Solitron Devices, Inc.'s commitment to implement processes to ensure conformance to each AS9100/ISO 9001 clause/element. The final paragraph in each section refers to the Standard Operating Procedures that describe in more detail how the activities are to be carried out. In some cases, these Standard Operating Procedures refer to Work Instructions, Test, and Assembly Procedures. All levels of Quality System Documentation are issued and authorized through Document Control.

3. PURPOSE

The purpose of this manual is:

- To document Solitron Devices, Inc.'s Quality system.
- To inform Solitron Devices, Inc.'s Customers of Process Controls that ensure Conformance to Requirements.
- To provide Guidance and Instruction to Solitron Devices, Inc.'s personnel whose work Impacts Quality.

Signed: _____ Date: _____
President/CEO

Signed: _____ Date: _____
Management Representative

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4. QUALITY MANAGEMENT SYSTEM

4.1. General Requirements

Solitron established a Quality Management System that complies with the AS9100/ISO9001 requirements and supports the Solitron Quality Policy and objectives. Quality at Solitron Devices, Inc. is based on the philosophy that all individuals and therefore their departments are responsible for Quality. This system identifies all of the processes necessary to enable a directed process approach that will

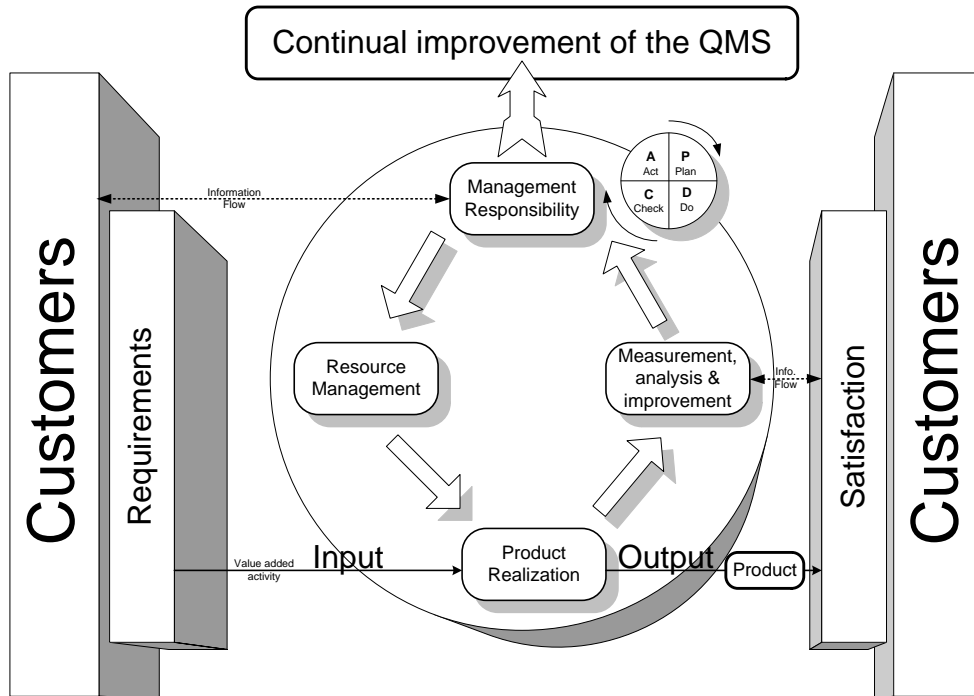
- Determine system processes and their application within Solitron Devices.
- Provide for development of sequential processes and interaction of the processes within the system .
- Define criteria and methods ensuring that Operation and Control of Processes are communicated throughout Solitron and are effective.
- Ensure that the necessary resources and information to support operation and monitoring of processes are in place.
- Monitor measure where applicable, and analyze the processes.
- Implement actions necessary to achieve planned results and continual improvement of processes.
- Ensure compliance with customer and applicable statutory and regulatory QMS Requirements.

Solitron ensures Control of outsourced processes using Inspection, Measurement and Analysis.

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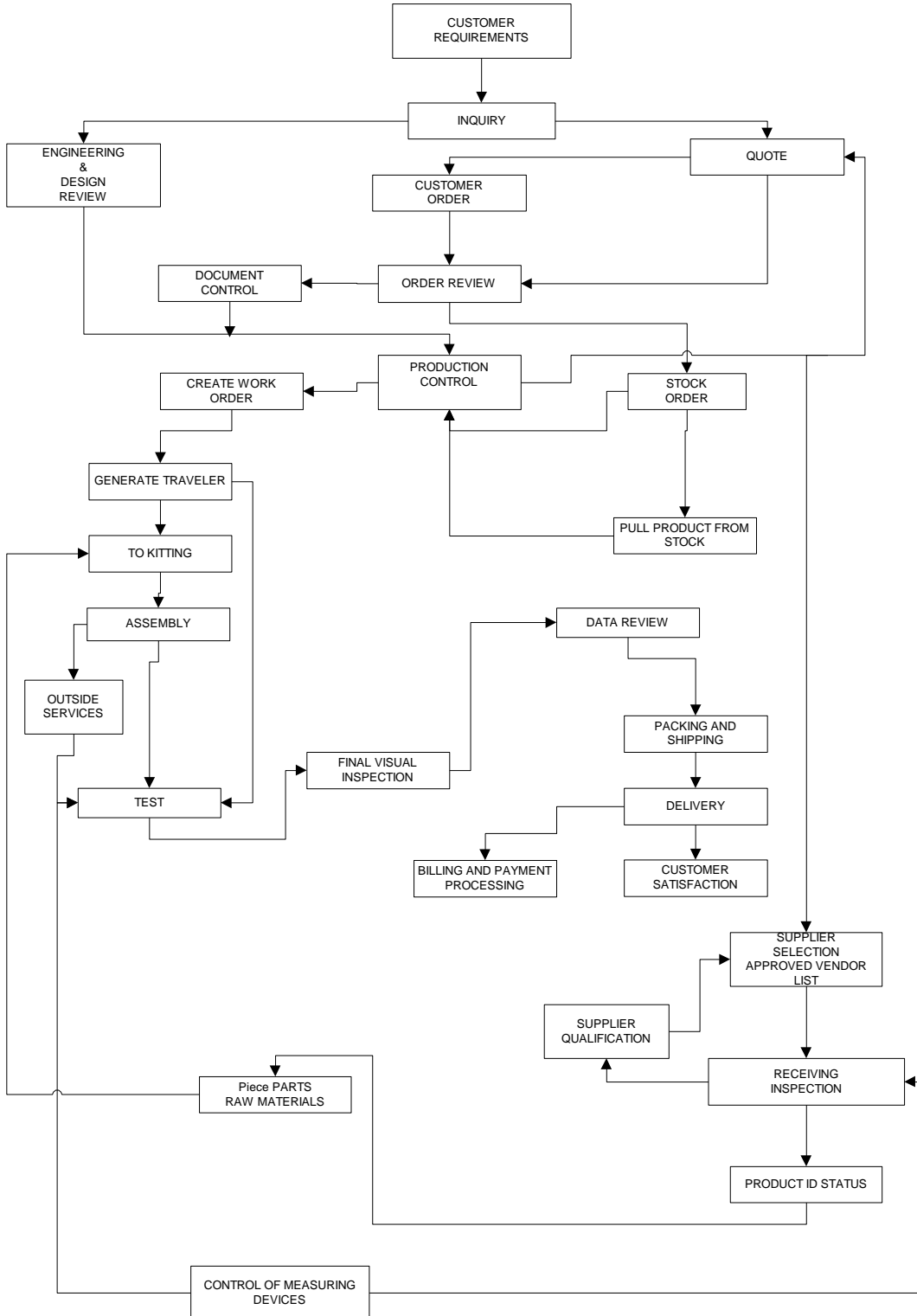


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SOLITRON QMS PROCESS INTERACTIONS



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4.2. Documentation Requirements

The Solitron Quality System documentation is structured as follows:

- **Quality Policy Manual -**
The first level document that provides a general overview of the Quality System and specifies the Quality Policy. This document describes the purpose for Solitron Devices, Inc. and "why" it is desired.
- **Quality Operating Procedures -**
The second level documents that provide more detailed explanation of the Quality System Elements. These documents explain how the Policies described in the Quality Policy are to be implemented - the "Who, What, Where and When". These are called Quality Operating Procedures (QOP's).
- **Work Instructions -**
The third level documents provide the "How to" follow the process or procedures, and do the work at the key company functional work centers. Work Instructions are best documented using flowcharts.
- **Other Instructions -**
The fourth level documents provide the "How to" do specific tasks. These documents include: Forms, Product Specifications, Task Instructions, Product Specific Drawings, Industry Standards, etc.

4.2.1. General

The Solitron Quality Management System documentation includes the following documented procedures as required by AS9100/ISO9001.

- Quality Manual (QPM 01)
- Document Control (QOP-05-01)
- Corrective and Preventative Action (QOP-14-01)
- Quality Records (QOP-16-01)
- Internal Auditing (QOP-17-01)
- Non-Conforming Product (QOP-13-01)
- Solitron Devices ensures that personnel have access to the Quality Management System documentation and are aware of relevant procedures and changes.

4.2.2. Quality Manual

Solitron Devices, Inc.'s Quality system is documented in the Quality Manual, the Associated Operating Procedures, and Work Instructions. The documents collectively define a quality system that complies with the AS9100/ISO9001 standard.

This Quality Policy Manual is approved by management, as shown on page 7, and is issued by the Quality Manager/Management Representative under the authority of the President/CEO. Implementation of the Quality System is regularly audited and reviewed.

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4.2.3. Control of Documents

4.2.3.1. General

Solitron Devices, Inc. has established and maintains documented procedures to control all documents and data that relate to the requirements of AS9100/ISO9001, including documents of external origin such as standards and customer drawings. The Document Control Department that reports to the QA Manager is responsible for coordination; enforcing and auditing the Document Control related activities. Quality System Documentation comprises the following types of documents:

- Quality Policy Manual
- Quality Operating Procedures
- Work Instructions, Test, Assembly, and Process Procedures
- Standards, Safety Agency, Compliance, and other Reference Material
- Product Drawings and Specifications

The purpose, scope, and responsibility for controlling each type of document are defined in QOP-02-01, "Quality System".

4.2.3.2. Document Approval and Issue

Documents and document changes may be initiated by anyone at Solitron Devices, Inc., but may only be issued by an authorized department described in procedures "Quality System", QOP-02-01, and "Document Control", QOP-05-01. All documents are reviewed and approved for adequacy prior to issue. A master list identifies the current revision status of documents and is available to all personnel to avoid the use of obsolete or invalid documents.

4.2.3.3. Control Documents

Documents are distributed to personnel and locations where they are used and invalid/obsolete documents are promptly removed to assure against unintended use. Obsolete documents retained for history purposes are identified as such by an "Obsolete" or "History" stamp. When appropriate and relevant, documents display a distribution list. Document placement is regulated and described in procedure "Document Control", QOP-05-01.

4.2.3.4. Document Changes

Document changes are reviewed and authorized by the same function/department that issued the original document. The nature of the change is identified in the document. Revised portions of documents are distributed with a RFC form (Request for Change form) and obsolete documents are removed.

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4.2.4. Control of Records

Solitron Devices, Inc. has established and maintains documented procedures for Control, Identification, Collection, Indexing, Access, Filing, Storage, Maintenance, and Disposition of Quality Records. Quality Records are maintained to demonstrate conformance to specified requirements and the effective operation of the Quality System. Pertinent sub-contractor Quality Records are also maintained. A Records Matrix is maintained by Document Control.

All Quality Records are legible and stored in designated filing cabinets by the departments responsible for their establishment, such that they are readily retrievable. The environment is controlled to minimize deterioration or damage and to prevent loss. Retention times of Quality Records are established and recorded. When agreed contractually, Quality Records are made available for evaluation by the customer for an agreed period.

The activities of Identification, Collection, Indexing, Access, Filing, Storage, Maintenance, and Disposition of Quality Records are described in procedure. The records are maintained according to procedure "Quality Records", QOP-16-01. The procedure defines the location and the departments responsible for keeping these records.

5. MANAGEMENT RESPONSIBILITY

5.1. Management Commitment

Solitron Devices, Inc.'s policy is that executive management is responsible for establishing and maintaining the quality system to support the Quality Policy. This includes:

- Defining the organization.
- Assigning authority and responsibility.
- Reviewing the Quality System.
- Providing the resources necessary to maintain the Quality System.
- Continually improve the effectiveness of the Quality Management System.
- Communicate to all Solitron personnel the importance of meeting Customer, Regulatory and Legal Requirements.

Solitron Devices, Inc. appoints the QA Manager as the Management Representative, with the authority and responsibility to ensure that the Quality Management System complies with the requirements of AS9100/ISO 9001. The management representative is assigned as the POC (point of contact) with the preparing activity (military or federal agency) with the authority and responsibility to coordinate all specification issues.

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5.1.1. Responsibility and Authority

PRESIDENT AND CHIEF EXECUTIVE OFFICER (CEO) –

Has the overall responsibility for the definition of, and adherence to, the Solitron Devices, Inc. Quality Policy. The President/CEO are responsible, through the QA Manager, for the authorization and the implementation of the Quality System throughout all areas of Sales & Marketing, Engineering, Operations and Finance. Specifically:

- Formulates the Quality Policy,
- Initiates and supervises the Quality System,
- Provides resources necessary to maintain the Quality System,
- Conducts management reviews of the Quality System.

FINANCE DIRECTOR –

Is responsible to the President/CEO for ensuring that all Corporate Finance activities and functions are operated according to the requirements stated in this manual. The Finance Director is responsible for ensuring that all Finance personnel are fully aware of the importance of product and service quality, and that the established procedures are followed throughout their respective departments.

ENGINEERING MANAGER –

Is responsible to the President/CEO for ensuring that the product designs, applications, and effectivity is established and maintained in a stable and consistent manner. The Engineering Manager oversees the design planning, activity assessment, verification and validation. The Engineering Manager oversees the technical interface within the company and recommends aids and methods used in calculations, test verification, and cost effectivity.

OPERATIONS DIRECTOR –

Is responsible to the President/CEO for ensuring that planning, procurement, verification and production activities are operated according to the requirements stated in this manual. The Operations Director is responsible for ensuring that Operations personnel are fully aware of the importance of product and service quality, and that established procedures are followed throughout their respective departments.

SALES MANAGER –

Is responsible to the President/CEO for ensuring that all sales and marketing activities and functions are operated according to the requirements stated in this manual. The Sales Manager is responsible for ensuring that all sales personnel are aware of the importance of product and service quality, and that established procedures are followed throughout their respective departments.

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Responsibility and Authority (continued)

PURCHASING MANAGER –

Is responsible to the President/CEO for ensuring that the Procurement activities are timely, complete, and cost effective. The Purchasing Manager provides interaction between production and outside vendors to coordinate the timely supply of items necessary for the production goals and operation of the factory.

QUALITY MANAGER (Management Representative) –

Is responsible to the President/CEO for directing and auditing all quality-related activities, and for reporting to, and advising the President and Executive Staff on all Quality matters. The Quality Manager is responsible for ensuring that all Solitron Devices, Inc., personnel are familiar with the company's Quality System and have the authority to ensure that the requirements of the system are implemented and maintained. The Quality Manager is also responsible for ensuring that the appropriate Quality Standards are available and that the standards are applied throughout the organization.

5.2. Customer Focus

Solitron Devices, Inc.'s policy is that each accepted request for quote, contract and order (statement of requirements) is reviewed by the Sales, Engineering, QA, and Manufacturing as appropriate, to ensure that:

- The requirements are adequately defined and documented. Where no written statement of requirement is available for an order received by verbal means, Solitron Devices, Inc. will ensure that the order requirements are agreed before their acceptance.
- Any contract or accepted order requirements differing from those in their quotation are resolved.
- Solitron Devices, Inc. has the capability to meet contract or accepted order requirements.
- Solitron Customer Satisfaction
- Top management ensures the 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.

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5.3. Quality Policy

At Solitron Devices, Inc. our Quality Policy is “Customer Satisfaction”; Solitron measures its performance against this goal through on time delivery, customer complaints, and returned material.

This Policy:

- Is appropriate to the purpose of Solitron Devices, Inc.
- Includes a commitment to meeting requirements and to continually improve the effectiveness of the Quality Management System.
- Provides a framework for defining, establishing, documenting and reviewing quality objectives.
- Is communicated and understood at the appropriate levels within the company.
- Is reviewed for continuing suitability.

5.4. Planning

5.4.1. Quality Objectives

Solitron Devices, Inc. has established corporate quality objectives, which have been deployed throughout the organization. The Quality objectives are consistent with the quality policy and the commitment to Continual Improvement. Quality objectives include those needed to meet the requirements of Solitron Devices product and processes as well as customer requirements. These objectives are reviewed Quarterly in Quality Management review meetings for continued suitability. Actions taken as a result of these meetings may be in the form of corrective action, preventative action or goal adjustments for the purpose of continuous improvement.

Objectives include:

- QA Pre-cap visual Inspection yields greater than 95%
- Resistance to Solvents yields greater than 95%
- Solderability yields greater than 97%
- Final Visual Mechanical Inspection yield greater than 98%

Solitron Devices management team provides a work environment that develops and rewards excellence. Employees are trained and empowered with skills and knowledge that enables them to deliver a product that is in accordance with its customers’ expectations. This philosophy is reflected in Solitron’s Quality Policy statement, which is communicated, understood within the organization and tracked through performance measurement charts, and statistics.

President/CEO _____

Operations Director _____

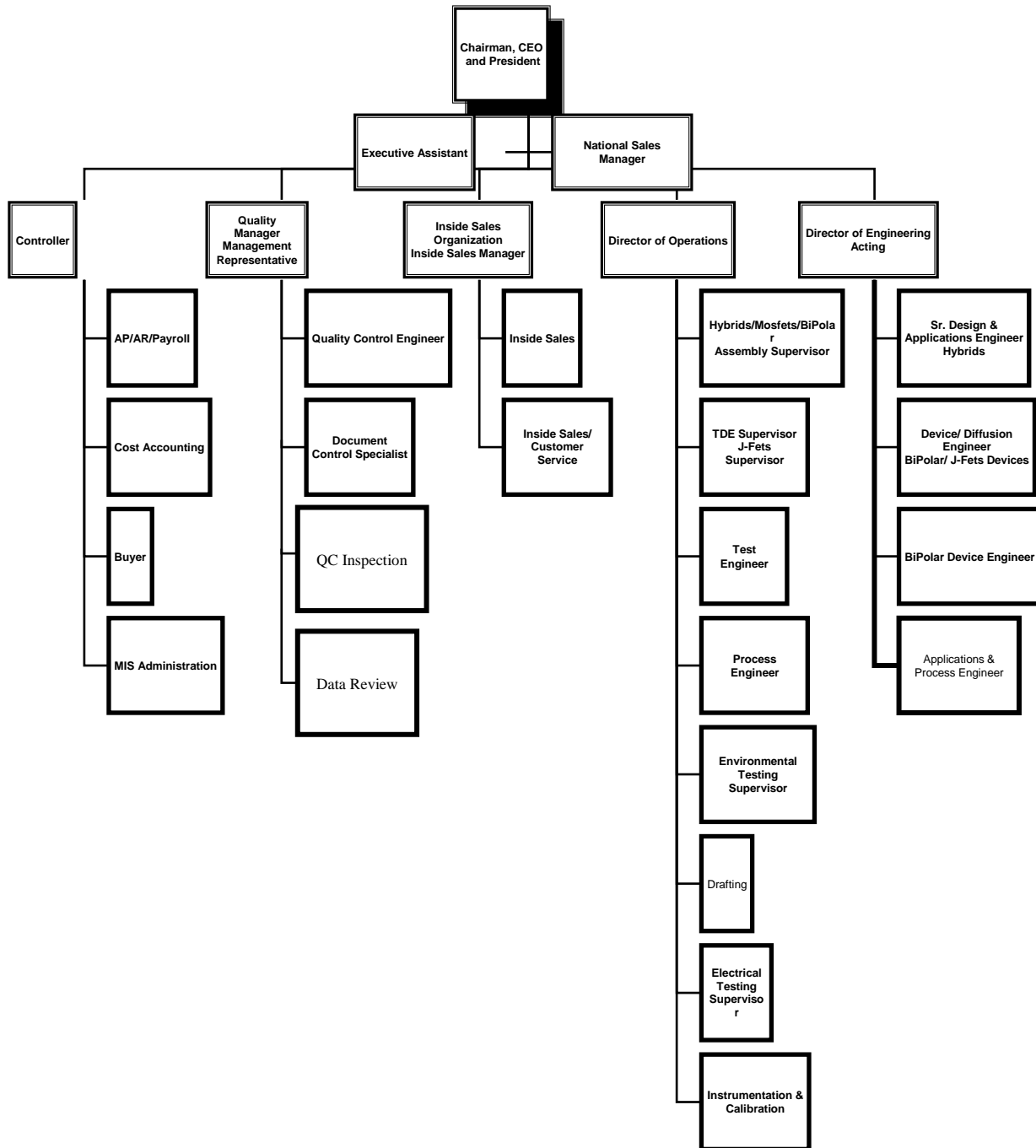
Management Representative _____

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Solitron Devices, Inc. Organizational Chart



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5.4.2. Quality Management System Planning

The contents of the Quality Policy Manual form the basic Quality Plan to which Solitron Devices, Inc.'s products are designed, manufactured and supported, unless a separate contract specific Quality Plan is required. Specific documentation is held at department level for the control of procedures and processes within that department. It is the responsibility of each functional operating department to define and implement processes, procedures, controls, and measurements that are necessary to assure that products meet the quality requirements of their internal and external customers. The requirements for each of the above documentation levels are referenced in paragraph 4.2. Technical References include: equipment-operating manuals, industry standards, purchased parts catalogs, etc.

Quality planning defines how the requirements for Quality will be met.

Information and Records - Recorded data of the Quality System and the results of the implementation. The "proof" that the policies, procedures, and work instructions were followed with resulting consequences that measures performance and offer opportunity for continuous improvement.

The Quality System, its make-up, how it is audited and reviewed is described in more detail in procedures QOP-17-01, "Internal Quality Audit", QOP-02-01 "Quality System" and QOP-01-01, "Management Review".

5.5. Responsibility, Authority, and Communication

5.5.1. Responsibility and Authority

Departmental Managers/Supervisors are responsible to and authorized by their respective managers for ensuring that all Solitron Devices, Inc. activities relating to their respective functions are operated according to the requirements stated in this manual. There is a unique job description written for each job function. The Managers and Supervisors are responsible for ensuring that all personnel are fully aware of the importance of product and service quality, and that established procedures are followed throughout their respective departments.

5.5.2. Management Representative

The QA Manager has been appointed as Management Representative and is responsible for the establishment, implementation, maintenance, and performance reporting of the Quality Management System to top management. The Quality Engineer is the alternate designee for the Management Representative. The Management Representative will communicate and promote awareness of customer requirements throughout the organization and has the organizational freedom and unrestricted access to top management to resolve matters pertaining to quality.

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5.5.3. Internal Communication

Quality Management System processes are communicated between various levels within the Solitron organization as follows.

- The Quality Manual.
- Operating Procedures and Work Instructions.
- Various weekly meetings i.e. Staff, Engineering, Quality, Sales, Production Control.
- Daily communication between Managers, Supervisors and other Employee's.

5.6. Management Review

5.6.1. General

On a weekly basis, Solitron Devices, Inc.'s Executive Staff conducts review and assessment of the Quality Management System to determine its effectiveness and continuing suitability. The review is based on the results of internal quality audits, customer feedback, non-conformances and corrective actions taken. The objectives of the review are to identify whether the Quality Management System is being implemented effectively, to identify inefficiencies or nonconformities in the system, and to suggest possible improvements. In addition Quarterly Management Review Meetings are attended by the President /CEO and the Quality Manager. The Quarterly Management Review meetings will include the weekly Management Review meeting minutes as input. The President/CEO is responsible for scheduling and conducting the reviews. Conclusions of the reviews are recorded. Details for scheduling, conducting and recording the reviews are provided in QOP-01-01, "Management Review".

5.6.2. Review Input

The agenda of Solitron management reviews will include assessment of current performance and improvement opportunities. The agenda activities are delineated in the document Management Review (QOP-01-01) paragraph 4.2. The objectives of the reviews are to insure the suitability, adequacy and effectiveness of the Quality Management System.

5.6.3. Review Output

The objective of the Management Review meetings is to obtain output in the form of decisions and actions. This "output" will insure the suitability, adequacy and effectiveness of the Quality Management System improve customer product and expose resource needs. Reference paragraph 4.3 of Management Review (QOP-01-01).

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6. RESOURCE MANAGEMENT

6.1. Provision of Resources

Department Managers/Supervisors have the opportunity to request the resources necessary to implement or enhance the Quality Management System or to Achieve Customer Satisfaction.

6.2. Human Resources

6.2.1. General

All personnel who manage, perform and verify work-affecting quality are responsible for implementing the Quality System. It is Solitron Devices, Inc.'s policy to provide adequate resources and assign trained personnel for all verification activities. Verification activities include inspection, test, production, servicing, monitoring of the design process and internal quality audits.

6.2.2. Competence, Training, Awareness

Solitron Devices, Inc. has established and maintains procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks are qualified on the basis of appropriate education, training and/or experience, as required. Records of personnel qualifications and training are maintained by QA.

“Training” procedure, QOP-18-01, describes in more detail the department Manager responsibilities, the training policy and training programs. All personnel are assessed annually by their Managers/Supervisors to determine if their qualifications are adequate and if additional or supplemental training is required.

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6.3. Infrastructure

Solitron Devices, Inc. has identified and planned the production, and servicing processes (customer returns only) that directly affect quality and ensures that these processes are carried out under controlled conditions. These controlled conditions include:

- Documented procedures defining the manner of production and servicing, where the absence of procedures could adversely affect quality.
- Use of suitable production, and servicing equipment, suitable working environment.
- Compliance with reference standards/codes, Quality Plans and/or Documented Procedures.
- Monitoring and Control of Process Parameters and Product Characteristics during Production, and Servicing.
- The approval of processes and equipment.
- Criteria for Workmanship Standards.
- Regular maintenance of equipment to ensure continuing process capability.
- Only trained operators or operators in training and under the Supervision of a certified operator or supervisor will perform processes.
- Process Controls and the development of Control Plans where key characteristics have been identified.
- Identification of in Process Verification points when adequate (verification of conformance cannot be performed at a later stage or realization).
- The Design, Manufactures, and use of tooling so that variable measurements can be taken particularly for key characteristics and special processes (see 7.5.2).
- Accountability for all Products during Manufacture (e.g., part quantities, split lots, nonconforming product).
- Evidence that all Manufacturing and Inspection Operations have been completed as planned, or as otherwise documented and authorized.
- Provisions for the Prevention, Detection, and Removal of Foreign Objects.
- Monitoring and Control of Utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect Product Quality.
- Criteria for Workmanship, which shall be stipulated in the clearest practical manner (e.g. written procedure, representative samples or illustrations).

The MOR (Material Order Request) form generated from the MRP system is used to start a job. A packet, consisting of a traveler, drawings, bill of materials, etc. defines the production plan, which is under the control of production. A traveler is generated identifying the verification and testing stages. Procedure "Process Control", QOP-09-01, describes the work order process in more detail.

When complexity or importance of an activity warrants it, production personnel are provided with procedures/work instructions. Production equipment, processes, product characteristics and production environment are controlled and/or maintained in accordance with procedure "Process Control", QOP-09-01.

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Activities associated with special processes are described in the procedure "Process Control", QOP-09-01.

6.4. Work Environment

Solitron Management has in place and maintains an infrastructure that enables compliance to product requirements. Solitron maintains a safe and healthy work environment that is in compliance with all applicable laws and regulations. In areas where chemicals are used Material Safety Data Sheets are maintained to provide guidance relative to physical and environmental issues. Solitron complies with all applicable laws and regulations relative to hazardous materials, air emissions and waste water disposal.

7. PRODUCT REALIZATION

7.1. Planning of Product Realization

To insure that Quality Objectives and product requirements are realized (*including support of operation and maintenance of product*) Solitron Devices, Inc. has established and maintains documented procedures for inspection and testing activities in order to verify that the specified requirements are met. The required Inspection, Testing, and the Records established are documented in procedures. Inspection and Testing are conducted when:

- Purchased materials and components are received
- At significant stages of production
- And prior to dispatch of finished products

The objective of inspection and testing is to verify conformance with specified requirements. Materials, Components and Products are prevented from use, assembly and dispatch until the required Inspections are completed. Records of Inspections and Testing are established and maintained as evidence that products comply with stated requirements.

7.1.1. Project Management

Solitron has in place a documented and maintained configuration Management Process that is appropriate to the product (QOP-02-02).

7.1.2. Risk Management

Solitron has in place a documented and maintained risk Management Procedure (QOP-02-04).

7.1.3. Configuration Management

Solitron has in place a documented and maintained configuration Management Process that is appropriate to the product (QOP-02-02).

7.1.4. Control of Work Transfers

When planning to temporarily transfer work to a location outside the Solitron facilities, Solitron defines the Process to Control and validate the Quality of the work.

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7.2. Customer Related Processes

7.2.1. Determination of Requirements Related to the Product

- Contract Review ensures that Customer Requirements are adequately defined, differences resolved and that Solitron Devices, Inc. has the capability to meet Customer Requirements.
- Solitron Devices, Inc.'s policy is that procedures for contract review and for the coordination of contract review activities are established and maintained (see paragraph 5.2).
- Original documents identifying Customer device drawing, revision date, etc. are retained in Document Control files.

7.2.2. Review of Requirements Related to Product

Solitron Devices, Inc.'s policy is that procedures for contract review and for the coordination of contract review activities are established and maintained. Ensuring that Solitron Devices, Inc. identifies how amendments to a contract are made and correctly transferred to functions concerned within the company. *This includes a review of risks (e.g. new technology, short delivery time scale) QOP-02-04 "Risk Management"*.

- Requirements are adequately defined and documented.
- Adequate company resources are available to meet customer requirements.
- Differences between the quotation and contract are addressed and resolved prior to acceptance of the order.
- Appropriate notification provided when contract/product amendments are required.
- The Sales Department maintains records of contract reviews.
- Special requirements are determined
- Risks are identified.

The contract review process is described in more detail in procedures QOP-03-01, "Contract Review".

7.2.3. Customer Communication

Solitron establishes and maintains Customer Communication utilizing letters, faxes, E-mail; telephone conversations, discussions and interaction during customer on site meetings, customer feedback and customer complaints.

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7.3. Design and Development

7.3.1. Design and Development Planning

Solitron Devices, Inc. has established and maintains documented procedures to control and verify the design of the product to ensure that the specified requirements are met.

Solitron Devices, Inc. designs standard and custom products. The Engineering Department is responsible for the design of the product. Quality assurance in design is described in more detail in procedure QOP-04-01, "Design Control".

Solitron Devices, Inc. prepares plans for each design and development activity, including defined responsibility, and describes or references these activities. The design and development activities are assigned to qualified personnel with the required resources.

All products have a "Design Check List" which identifies the activities to be performed and the associated responsibilities.

The Design Check List may be updated periodically to reflect actual activity steps and their status as the design evolves. The initiation, tracking, and completion of the Design Check List are the responsibility of the Engineering Department.

Organizational and technical interfaces between different groups that input to the design process are identified and information is documented, distributed and regularly reviewed. The "Design Check List" maintained by the Engineering Department identifies these interfaces.

The design plan includes:

Design and development stages including organization, task sequence, mandatory steps, significant stages and method of configuration control.

- Where appropriate, Solitron shall divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, input and output data and planning constraints.
- Structuring the design effort into significant elements.
- For each element, analyzing the tasks and necessary resources for its design and development. This analysis considers an identified responsible person, design content, input data, planning constraints and performance conditions. The input data specific to each element is reviewed to ensure consistency with requirements.
- The different design and development tasks to be carried out shall be based on the safety and functional objectives of the product in accordance with customer, statutory and regulatory requirements.

7.3.2. Design and Development Inputs

Design input requirements including statutory and regulatory requirements are identified, documented and their selection reviewed by the Engineering Department for adequacy. The Functional Product Requirement document identifies the initial needs to be fulfilled by the product, including applicable information from similar designs. Design input requirements are identified, documented and reviewed for accuracy by the Engineering Department. Incomplete, ambiguous or conflicting requirements are resolved with the Engineering Department and applicable Customer Representatives. The process is described in more detail in procedure QOP-04-01, "Design Control".

7.3.3. Design and Development Outputs

Design output specifications are documented and expressed in terms of requirements that can be verified. The Engineering Department review design outputs to ensure that:

- Design input requirements are met.
- Acceptance criteria are clearly stated.
- Appropriate safety and regulatory requirements are met.
- Characteristics of the design that are crucial to the safe and proper functioning of the product are identified.
- Outputs provide necessary information for purchasing, production and service provision.
- Key characteristics (when applicable) are identified in accordance with design or contract requirements.

Data required to allow the product to be identified, manufactured, inspected, used and maintained are defined:

- Drawings, parts lists, specifications.
- A list of those drawings, parts lists and specifications necessary to define the configuration and the design feature of the product.
- Information on material, processes, type of Manufacturing and Assembly data needed to ensure conformity of the product.

Establishment, verification and release of design output are described in procedure QOP-04-01, "Design Control".

7.3.4. Design and Development Review

At appropriate stages of design, formal documented reviews of the design results are planned and conducted. The participants at each design review may include the Process Engineer, Test Engineer, Production, QA and the customer representative if required by contract. The review will address all aspects of design and development including quality-related requirements, identification of possible problems and necessary follow up actions resulting in authorization to progress to the next step. The process is described in more detail in procedure QOP-04-01, "Design Control". Records of these reviews are maintained by the Engineering Department as detailed in procedure QOP-16-01, "Quality Records".

7.3.5. Design and Development Verification

Design verification is performed at appropriate stages to ensure that the design stage output meets the design stage requirements. Verification that design output meets design input requirements is achieved by holding and recording design reviews, undertaking qualification testing of the first article and performing alternative calculations. The design verification measures are recorded by the Applications Engineers as detailed in procedure QOP-16-01, "Quality Records". Design verification activities are described in procedure QOP-04-01, "Design Control".

7.3.6. Design and Development Validation

Our customer normally does design validation of our product. However, where the contract specifies, we can support our customer's effort where possible. Validation is the responsibility of the Engineering Department and is described in procedure QOP-04-01, "Design Control".

7.3.7. Control of Design and Development Changes

All design changes and modifications are initiated by completing a RFC, Request for Change form. The information provides design input for the changes and is controlled via the change procedure, which requires appropriate approval and review of changes and modifications.

Planning, design output, and design verification activities follow the same rules as applied to the original design and are described in procedure QOP-04-01, "Design Control".

Design and development changes shall be controlled in accordance with the configuration process (see 7.1.3).

Note: The Solitron change control process shall provide for customer and/or regulatory approval of changes, when required by contract or regulatory requirements.

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7.4. Purchasing

7.4.1. Purchasing Process

Solitron Devices, Inc. has established and maintains documented procedures to ensure that purchased product conform to specified requirements. Solitron Devices, Inc. evaluates its suppliers and subcontractors and purchases only from those that can satisfy the company's quality requirements. Purchasing documents clearly and completely describes ordered products, including quality requirements. Purchasing documents are reviewed and approved prior to release.

Solitron Devices, Inc. evaluates and selects subcontractors on the basis of their ability to meet subcontract requirements including quality system and quality assurance requirements. The type and extent of the control exercised by Solitron Devices, Inc. on our subcontractors is dependent on the type of product/service, and where applicable the quality audit reports and/or quality records of subcontractors' previously demonstrated capability and performance. Solitron Devices shall be responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer. Solitron will also ensure (where required) that customer-approved special process sources are used. This includes all Solitron supplier use.

Solitron shall:

- Maintain a register of approved its suppliers that includes approval status (e.g. approved, conditional, disapproved) and the scope of the approval (e.g. product type process family).
- Periodically review supplier performance; the results of these reviews shall be used as a basis for establishing the level of controls implemented.
- Define the necessary actions to take when dealing with suppliers that do not meet requirements.
- Ensure where required that both Solitron and all suppliers use customer-approved special process sources.
- Define the process responsibilities and authority for approval status decision, changes of approval status and condition and conditions for a controlled use of suppliers depending on their approval status.
- Determine and manage the risk when selecting and using suppliers.

Quality performance of all suppliers and subcontractors is monitored. Vendors showing inadequate performance are asked to implement corrective actions and are discontinued if there is no improvement. Quality maintains an approved supplier/subcontractor-rating list. Orders may only be placed with vendors that are rated as approved on the list unless specifically approved by quality. New vendors are added to the list for evaluation at the point of initial order. Records of acceptable subcontractors/suppliers are maintained. Detailed instructions for assessment of sub-

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contractors/suppliers are provided in procedure QOP-06-01, "Subcontractor Evaluation".

7.4.2. Purchasing Information

The Production Control Manager prepares purchasing documents. The documents clearly and completely describe ordered products. They include precise identification of the products, reference applicable standards and state quality requirements. The President/CEO approves all purchasing requests. QA and the Controller must review/approve all P/O's to ensure the adequacy of the requirements before the orders are placed with the supplier. However, if over \$5000, the President must also sign the P/O. Rules applicable to preparation, review and approval of purchasing documents are provided in procedure QOP-06-02 "Purchasing".

The purchasing information shall describe the product to be purchased, including where appropriate.

- The identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data.
- Requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by Solitron, and its applicable critical items including key characteristics.
- Requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing.
- Requirements regarding the need for the supplier to notify Solitron of nonconforming product and obtain Solitron approval for nonconforming product disposition. Notify Solitron of changes in product and/or process, changes of suppliers, change of manufacturing facility location and where required, obtain Solitron approval and flow down to the supply chain the applicable requirements including customer requirements.
- Record retention requirements.
- Right of access by Solitron, their customer and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved on the order and to all applicable records.

Solitron shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3. Verification of Purchased Product

Where Solitron Devices, Inc. verifies purchased product at the subcontractor/supplier's facilities, the verification arrangements and the method of product release are specified in the purchasing documents as detailed in procedure QOP-06-01, "Subcontractor Evaluation" and QOP-06-02 "Purchasing".

Verification activities can include:

- Obtaining objective evidence of the conformity of the product from the suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control records).
- Inspection and audit at the supplier's premises.
- Review of the required documentation.
- Inspection of products upon receipt.
- Delegation of verification to the supplier, or supplier certification.

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

When Solitron utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. Solitron shall periodically validate test reports for raw material.

Where Solitron delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.

When Solitron or its customer intends to perform verification at the supplier's premises, Solitron shall state the intended verification arrangements and method of product release in the purchasing information.

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Verification of Purchase Product (continued)

When specified in the contract, Solitron Devices, Inc.'s customers have the right to verify at the subcontractor/supplier facilities that the product conforms to specified requirements. This customer verification does not absolve Solitron Devices, Inc. from the responsibility of providing acceptable product or preclude subsequent rejection by the customer. Solitron Devices, Inc. as evidence of effective control of quality does not use the customer verification by the subcontractor.

Consideration is given to the amount of control exercised at the subcontractor/supplier's premises and recorded evidence of conformance provided. All products are inspected visually, and then are subjected to a more detailed and technical inspection and/or testing. Nonconforming products are handled using an IMIR (Incoming Material Inspection Report) form. They are segregated and are prevented from use in production. The procedure, "Receiving Inspection and Testing", QOP-10-01, describes the activities and recording processes.

7.5. Production

7.5.1. Control of Production

Solitron Devices, Inc. has established and maintains documented procedures for control of production (see Para. 6.3 Infrastructure) customer returned material using the Return Material Authorization (RMA) procedures. Solitron Devices, Inc.'s procedures for Return Material Authorization include:

- Rejection report from customer.
- Review report to approve return or require engineering sample.
- Sales to log RMA and notify customer to return product.
- Sales enter debit/credit line item information.
- Receive product from customer, log and verify proper paperwork.
- Engineering to indicate pre-disposition instructions on RMA to verify or refute customer complaint.
- Engineering will disposition product for replacement or rework.
- Production Control enters into WIP (Work In Process) tracking database.
- Engineering/Production carry out disposition.
- Final QA visual and data review.
- Return to customer.
- Corrective action prepared and submitted to customer if required.

Servicing Procedure QOP-19-01 describes the responsibilities and activities of customer returns (RMA's).

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Corrective and Preventive Action QOP-14-01 describes the responsibilities and activities of corrective action.

Rework Procedure QOP-13-03 describes the responsibilities and activities of rework.

7.5.1.1. Production Process Verification

Production operations shall be carried out in accordance with approved data. This data shall contain as necessary.

- Drawings, parts lists, process flow charts, procedures including inspection operations productions documents (e.g. manufacturing travelers, process cards) and inspection documents.
- A list of specific or non-specific tools and any specific instructions associated with their use.
- Based on customer requirements the Solitron system shall provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result.

7.5.1.2. Control of Production Process Changes: Personnel authorized to approve changes to production processes are identified.

Solitron shall identify and obtain acceptance of changes that require customer and/or regulatory requirements.

Changes affecting processes, production equipment, tools and programs are being documented. Procedures are available to control their implementation.

The results of changes to production processes are assessed to confirm that the desired effect has been achieved without adverse effects to the product quality.

7.5.1.3. Control of Production Equipment, Tools and Programs

Production equipment tools and programs are validated prior to use, maintained, and inspected periodically according to documented procedures. Where applicable validation prior to production use will include verification of the first article produced to the design data/specification.

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

7.5.1.4. Control of Service Operations N/A (Customer returns only) see QOP-19-01.

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7.5.2. Validation of Processes for Production

Solitron Devices, Inc. has established and maintains documented procedures identifying the inspection and test status of product through production, and servicing to ensure that only product that has passed the required inspection and tests is dispatched, or used. The inspection and test status of product is identified, indicating the conformance or nonconformance of product with regard to inspections and tests performed.

Note: These processes are often referred to as special processes.

Authority responsible for the release of conforming product is defined.

Inspection status, identification system and measures to prevent product from being used or dispatched before it passes the prescribed inspections are described in procedure "Inspection and Test Status", QOP-12-01.

The Supervisor ensures that Inspection and Test Status is controlled throughout the entire process. Products that pass the receiving inspection are placed in stock. Products that fail at receiving inspection are identified with a red "reject" tag and IMIR and moved to the M.R.B. (Material Review Board) holding area.

In-process inspection and test status is identified on a traveler accompanying the product.

Products that pass the final inspection and test are identified by a certificate of compliance.

Products that fail in-process/final inspection and test are identified and segregated.

The QA Manager (or designee) has the authority to release product for shipment. The final test results and all pertinent documentation are retained forming the data pack.

7.5.3. Identification and Traceability

Solitron Devices, Inc. has established and maintains documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery and servicing. Parts / materials are identified by a part number and/or lot number / in ship number correlated to corresponding drawings, specifications and other technical documents. Indication of Inspection Status Procedure QOP 12-01. Acceptance authority media "stamps" are controlled using Procedure QOP-12-02 (Inspection Stamp Control). Rework Procedure QOP 13-03.

All purchased and in-house manufactured materials and parts are identified with Solitron Devices, Inc.'s internal part numbers assigned by engineering through document control. The part numbers provide for a correlation

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between a part and its technical documentation. Finished products are labeled with a lot number to allow for traceability of product configurations including sub-assemblies where applicable.

Identification and Traceability (continued)

Quality maintains the part number lists and associated technical documentation. The part number of a product is the key to correlation with its parts lists, technical documentation and quality records. Procedure "Product Identification and Traceability", QOP-08-01, describes this process in more detail.

7.5.4. Customer Property

Solitron Devices, Inc. has established and maintains documented procedures for verification, storage and maintenance of customer supplied product provided for incorporation into the supplies. Customer supplied products are handled in the same manner as other products purchased for incorporation into the supplies. When specified by the client, special handling instructions from customers will take precedent over Solitron Devices, Inc.'s standard procedures. Customer property can include intellectual property and personal data. Loss, damage, deterioration or unsuitability of customer-supplied products are recorded, and reported to the customer. Customer supplied products are reviewed, inspected, tested, marked and stored in the same manner as other purchased products. Procedure "Customer Supplied Product", QOP-07-01, contains detailed instructions.

7.5.5. Preservation of Product

Solitron Devices, Inc. has established and maintains documented procedures/and or training for:

- Handling
- Storage
- Packaging
- Preservation and delivery of product
- Marking and Labeling
- Shelf life control and stock rotation
- Hazardous material handling

The Operations Manager is responsible for preventing damage or deterioration of products through handling, storage, packaging, preservation and delivery. Procedure "Product Handling", QOP-15-01, describes the processes to ensure that containers are adequate and clean, that equipment used for internal transportation of product is well maintained and operators are trained in use of the equipment, and that product is protected during production, storage and delivery. All personnel handling electronic components and sub-assemblies are trained in E.S.D. protection techniques.

The storage areas and their operation are the responsibility of Production Control. Designated storage areas and stock rooms are used to prevent

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damage or deterioration of product, pending use or delivery. Methods for receipt and dispatch to and from these areas are stipulated and described in more detail in procedure "Storage", QOP-15-02.

Preservation of Product (continued)

Only products that are properly identified and that have passed the mandatory inspections are authorized to enter and leave the storage areas. During cycle counts, the storage areas are inspected to assess the condition of stock. Personnel storing electronic components and sub-assemblies are trained in E.S.D. protection techniques.

Packing, packaging and marking processes are controlled to the extent necessary to ensure conformance to specified requirements. Methods for preservation and segregation of products are applied when under the control of Solitron Devices, Inc. The protection of quality of products is maintained after final inspection and test, and where contractually specified, extended to include delivery to destination.

Packaging is specified by Engineering (or when specified in the contract) Preservation and Delivery is under the control of the Operations Manager. After the final inspection, products are protected and stored in protective packages under controlled environmental conditions to prevent damage and deterioration. If delivery is specified, it is subcontracted only to carriers on the AVL.

The activities of Packaging, Preservation and Delivery are described in procedure "Packaging, Preservation and Delivery", QOP-15-03.

7.6. Control of Monitoring and Measuring Equipment

Solitron Devices, Inc. has established and maintains documented procedures to control, recall and maintain inspection, measuring and test equipment (including test software) requiring calibration that is used to demonstrate the conformance of product to the specified requirements.

Inspection, measuring and test equipment is used in a manner that ensures that measurement uncertainty is known and is consistent with the required measurement capability.

Where test software or test hardware are used as inspection/testing tools, they are checked to prove that they are capable of verifying the acceptability of product prior to release for use during production, and servicing. These tools are re-checked at prescribed intervals. The extent and frequency of checks and maintenance of records as evidence of control are defined in procedure "Inspection, Measuring and Test Equipment", QOP-11-01. Where the availability of technical data relating to measurement devices is a specified requirement, the data will be made available, when required by the customer, for verification that the devices are functionally adequate. When specified in the equipment contract, Engineering determines the

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measurements to be made, the accuracy required, selects the appropriate inspection, measuring, and test equipment that is capable of the accuracy and precision necessary.

Control of Monitoring and Measuring Equipment (continued)

QA identifies all inspection, measuring and test equipment including measurement devices that can affect product quality, calibrates, and adjusts them at prescribed intervals, or prior to use, against certified equipment having traceability to national standards. Where no such standard exists, the basis used for calibration is documented.

QA defines the process for calibration of inspection, measuring and test equipment including details of equipment type, identification, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory.

QA is responsible for identifying calibration status of inspection, measuring and test equipment with calibration stickers.

QA maintains calibration records for inspection, measuring and test equipment.

QA assesses and documents the validity of previous inspection and test results when inspection, measuring and test equipment is found to be out of calibration.

QA ensures that the environmental conditions are suitable for the calibration, inspections, measurements and tests being performed.

QA ensures that the handling, preservation and storage of inspection measuring and test equipment are such that the accuracy and fitness for use is maintained.

QA safeguards inspection, measuring and test facilities, including test hardware/software, from adjustments, which would invalidate the calibration setting.

All control of inspection, measuring and test equipment and calibration related activities are documented in procedure "Inspection, Measuring and Test Equipment", QOP-11-01.

8. MEASUREMENT ANALYSIS AND IMPROVEMENT

8.1. General

Solitron Devices has in place the necessary methods and procedures to facilitate the assessment of product conformance and to achieve improvement in the areas deemed necessary within the Quality System.

QOP-01-01 Management Review –

Primary function is to assess and enhance the Solitron Management System.

QOP-04-01 Design Control –

The purpose of this procedure is to provide for implementation and assessing responsibilities for product design control and design verification.

QOP-13-01 Non-Conforming Product –

To provide for implementation and assignment of responsibilities for identifying and documenting a “non-conformance”.

QOP-14-01 Corrective and Preventative Action –

To provide for implementation and assigning responsibilities for initiating, requesting, implementing and checking the effectiveness of corrective and preventative action.

QOP-17-01 Internal Audits –

Provides a plan for continual assessment of the Quality Management System.

QOP-20-01 Statistical Techniques –

This procedure provides for implementation and assigning responsibilities for the use of statistical techniques. Statistical techniques may be used to support:

- Design verification (e.g., reliability, maintainability, safety)
- Inspection and Failure mode and effect criticality analysis
- Process Controls
 - Selection and Inspection of Key Characteristics
 - Process Capability Measurements
 - Statistical Process Control
 - Design of Experiment

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8.2. Monitoring and Measurement

8.2.1. Customer Satisfaction

Customer satisfaction is evaluated by utilizing customer communication and feedback (i.e. customer satisfaction survey, vendor rating, RMA's, telephone contacts, e-mail, faxes, on site meetings, sales visits).

8.2.2. Internal Audit

Solitron Devices, Inc. has established and maintains documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Internal quality audits on each critical process step are performed at least once each year. These audits are scheduled and based on the status and importance of the activity being audited. The audits are performed by personnel independent of those having direct responsibility for the activity being audited.

Audit results are recorded and brought to the attention of personnel having responsibility in the area audited. The management personnel responsible for the area respond with a corrective action on the deficiencies within the time frame specified on the audit noncompliance report. Follow-up audit activities record the implementation and effectiveness of the corrective action taken.

The QA Manager is responsible for establishing an internal audit plan and schedule in accordance with procedure "Internal Quality Audit", QOP-17-01. The QA Manager leads the audit team. QA activities are audited by Independent Auditors. Every functional area is audited at least once a year, but more frequent audits may be scheduled if required.

8.2.3. Monitoring and Measurement of Processes

Solitron Quality system processes are monitored using the following techniques:

- Internal Quality Audits
- Corrective and Preventative Action Trends
- Measuring and Monitoring Customer Satisfaction (see Para. 8.2.1)
- Review of Product Conformity and Quality Performance data.

In the event of process nonconformity, Solitron shall:

- Take appropriate action to correct the nonconforming process.
- Evaluate whether the process nonconformity has resulted in product nonconformity.

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- Determine if the process nonconformity is limited to a specific case or whether it could have affected processes or products.
- Identify and control any nonconforming product in accordance with clause 8.3.

8.2.4. Monitoring and Measurement of Product

In-process inspection and testing are specified on procedures/work instructions. Product is held until the required inspection and test have been completed or necessary reports have been received and verified. The procedures/work instructions travel with the product in the traveler folder. All activities associated with in-process inspection and testing are described in procedure "In-process Inspection and Testing", QOP-10-02.

All finished products are subjected to final inspection and testing. This is in accordance with documented procedures. Records of final inspection and testing provide evidence of conformance of finished product to specified requirements. All specified inspection and tests, including those specified on receipts of product and in process, are performed. Only those products/services that pass all stages, and have associated test/verification data authorized by the QA Manager (or designee) are admitted to finished products inventory or can be shipped. Performing and recording final verification is described in procedure "Final Inspection and Testing", QOP-10-03.

When critical items, including key characteristics have been identified, Solitron ensures that they are monitored and controlled in accordance with established processes.

When Solitron uses sampling inspection as a means of product acceptance, 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 capability).

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

All inspections and tests are recorded and signed off by the personnel performing the inspection/testing. Controls for establishing the inspection records are described in the Receiving/In-process/Final Inspection and Testing procedures listed above. Records, which provide evidence that the product has been inspected and/or tested, are maintained and controlled as indicated in procedure "Quality Records", QOP-16-01. These records show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. When product fails to pass any inspection and/or test, the procedure "Control of Nonconforming Product", "QOP-13-01, applies.

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Where required to demonstrate product qualification Solitron shall ensure that records provide evidence that the product meets the defined requirements

Solitron shall insure that all documents required to accompany the product are present at delivery.

8.2.4.1. Inspection Documentation

Measurement requirements for product or acceptance shall be documented. This documentation may be part of the production documentation, but shall include:

- Criteria for acceptance and/or rejection.
- Where in the sequence measurement and testing are performed.
- Required records of measurement results (at a minimum indication of acceptance or rejection).
- Any specific measurement instruments required and any specific instructions associated with their use.

8.3. Control of Nonconforming Product

Solitron Devices, Inc. has established and maintains documented procedures to ensure that product that does not conform to specified requirements is prevented from inadvertent use. Control provides for identification, documentation, evaluation, segregation (when practical), and disposition of nonconforming product and for notification to the functions concerned.

Note: The term “nonconforming product” includes nonconforming product returned by a customer.

Solitron procedures define the responsibility for review and authority for the review and disposition of nonconforming product and the process for approving personnel making these decisions.

The Material Review Board is responsible for the review and disposition of nonconforming product. Nonconforming product is reviewed in accordance with documented procedures and may be:

- Reworked or repaired to meet specified requirements;
- Accepted, with or without repair by concession;
- Re-graded for alternative applications;
- Rejected or scrapped.

When required by contract, the proposed use or repair of product that does not conform to specified requirements is reported to the customer for concession. The description of nonconformity that has been accepted, and of repairs made, are recorded to denote the actual condition and kept as part of the quality records.

Solitron shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if the nonconformity results in a departure from the contract requirements.

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Unless otherwise restricted in the contract, Solitron designed product which is controlled via a customer specification may be dispositioned by Solitron as use-as-is or repair only after approval by an authorized Solitron engineer responsible for design.

Control of Nonconforming Product (continued)

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

Repaired or reworked products are re-inspected in accordance with "Inspection and Testing" procedures, QOP-10-01, QOP-10-02, or QOP-10-03, as applicable.

Nonconformity review, disposition and recording of these activities are described in more detail in procedure "Control of Nonconforming Product", QOP-13-01.

In addition to any contract or regulatory authority reporting requirements, the Solitron nonconforming product control process provides for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification shall include a clear description of the nonconformity, which includes as necessary parts affected, customer and/or Solitron part numbers, quantity and date(s)

Note: Parties requiring notification of nonconforming product may include suppliers, internal organizations, customers, distributors, and regulatory authorities.

8.4. Analysis of Data

Statistical techniques is the use of statistical tools such as Check Sheets, Process Flow Charts, Histograms and Pareto Charts to analyze a process or its outputs so as to take appropriate actions to achieve and maintain a state of statistical control and improve the process capability. Solitron Devices, Inc. has established, documented and maintained procedures to implement and control the application of statistical techniques.

Solitron Devices, Inc. has identified the need for statistical techniques for establishing, controlling and verifying process capability and product characteristics within the manufacturing / operations functions. This includes Receiving Inspection, In-Process Inspection and Testing, and Final Test activities.

Qualified personnel, using statistical methods, are provided with charts, tables and other instructions in the use of these techniques. "Statistical Techniques" procedure, QOP-20-01, describes the activities in more detail.

SOLITRON DEVICES, INC.

QUALITY POLICY MANUAL

QPM01

8.5. Improvement

8.5.1. Continual Improvement

Continual improvement is driven by the Solitron Quality Policy and Quality Objectives. Continual improvement needs are identified and monitored with the use of internal quality audits, product and process performance data, vendor performance data, corrective and preventative action data.

8.5.2. Corrective Action

Solitron Devices, Inc. has established and maintains documented procedures for implementing corrective and preventive action. Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and the risks encountered. Any changes resulting from corrective and preventive actions are implemented and recorded in the appropriate affected procedures.

Solitron Devices, Inc.'s procedures for corrective action include:

- The effective handling of customer and service complaints, and other internal or external reports of product nonconformities.
- Investigating the cause of nonconformities relating to product, processes and quality system, and recording the results of the investigation.
- Determining the corrective action needed to eliminate the cause of nonconformities.
- Based on the causes of any non-conformance determining if additional non-conforming product exists and take action when necessary.
- Applying controls to ensure that corrective action is taken and that it is effective.
- Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the nonconformity.
- Specific actions where timely and/or effective corrective actions are not achieved.
- Determining if an additional nonconforming product exists based on the causes of the nonconformance and taking further action when required.

8.5.3. Preventative Action

Solitron Devices, Inc.'s procedures for preventive action include:

- The use of appropriate sources of information such as processes and work operations which affect product quality, nonconformance reports, audit results, quality records, service reports and customer complaints to detect, analyze and eliminate potential causes of nonconformities.
- Determining the steps needed to deal with any problems requiring preventive action.
- Initiating preventive action and applying controls to ensure that it is effective.
- Ensuring that relevant information on actions taken, including changes to procedures, is submitted for management review.
- Reviewing the effectiveness of the preventative action taken.

Anyone in the company may propose initiation of a Corrective/Preventative Action, but only the Quality Manager can authorize the "Corrective/Preventative Action Request" form. Each action is followed up by the Quality Manager to determine if the Corrective/Preventative Action has been implemented and if it is effective. The process of initiating a corrective/preventative action request, documenting the proposed action and the follow-up are described in procedure "Corrective and Preventive Action", QOP-14-01.