



Quality Management Manual



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USA 91352**



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Introduction

Solara Engineering/Zenith Mfg./Zenith Mfg. developed and implemented a Quality Management System in order to document the company's best business practices to better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The Quality Management System of Solara Engineering/Zenith Mfg./Zenith Mfg. meets the requirements of the international standard AS9000. This system addresses the design, development, production, installation, and servicing of the company's products.

The manual is divided into eight sections that correlate to the Quality Management System sections of the ISO 9001:2000 format and AS 9000. Each section begins with a policy statement expressing Solara Engineering/Zenith Mfg./Zenith Mfg.'s obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the AS 9100 standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

President: _____

Vice President: _____

Director of Quality: _____

Quality Manager: _____

Distribution

Controlled copies of the Quality Management System will be distributed as follows:

Quality Manager/Management Representative (Master Copy)

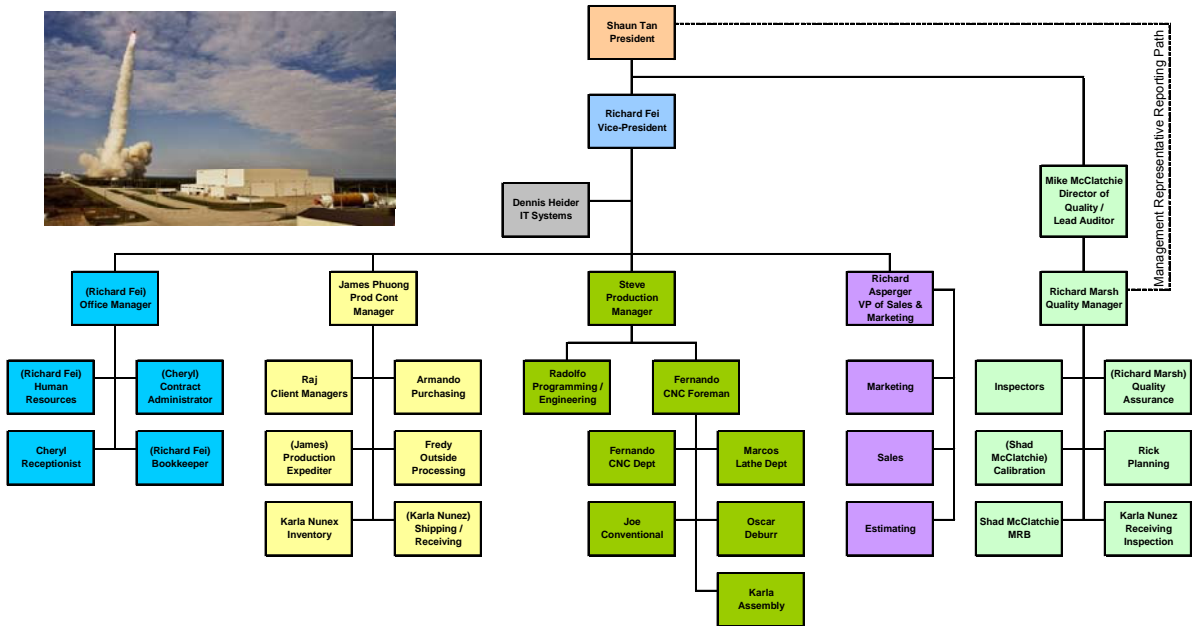
Inspection Department (for review by all employees)

All QMS documentation including this manual, procedures, forms, attachments, and work instructions will be made available to Company personnel via the Company intranet.

Uncontrolled copies of the Quality manual will be made available to Customers, Vendors, and Regulatory Agencies as requested.

Organizational Chart

February 4, 2008



QMM Revision Record

Revision	Description	Section(s)	Date	QA Manager
A	ISO 9002 Procedures developed for Sections OP-3-1 through OP-20-1	OP-3-1 to OP-20-1	09/24/98	M. Lee (signature on file)
B	Initial Release QMS D6-84279 as supplemented by AS9100-1999-11 including ISO 9002:1994 and D1-9000 AQS Revision A. Obsoleted manual Revision A	QAM 1.1 to 20.5	03/05/01	M. Lampron (signature on file)
C	Initial Release ISO9001:2000 as supplemented by AS9100 Rev A Section 1 and BQMS D6-82479 Appendix A Addendum 1. Obsoleted manual Revision B.	QAM 4.1 to 8.5	12/15/03	M. McClatchie (signature on file)
D	Secondary Release ISO9001:2000 as supplemented by AS9100 Rev A Section 1 and BQMS D6-82479 Appendix A Addendum 1. Obsoleted manual Revision C.	QAM 1 to QAM 8.5	03/31/04	M. McClatchie (signature on file)
E	Tertiary Release ISO9001:2000 as supplemented by AS9100 Rev A Section 1, BQMS D6-82479 Appendix A Addendum 1 and D6-51991 Rev G. Obsoleted manual Revision D	QAM 1 to Addendum 2	12/31/04	M. McClatchie (signature on file)
F	Quaternary Release ISO9001:2000 as supplemented by AS9100 Rev A Section 1, BQMS D6-82479 Appendix A Addendum 1 and D6-51991 Rev G. Obsoleted manual Revision E	QAM 1 to Addendum 2	04/06/05	M. McClatchie (signature on file)
G	5 TH Release ISO9001:2000 as supplemented by AS9100 Rev A Section 1, BQMS D6-82479 Appendix A Addendum 1 and D6-51991 Rev G. Re-format manual and added Addendum III and changed addendum II back to customer specific per customer rep. Obsoleted manual Revision E	QAM 1 to Addendum III	12/8/05	M. McClatchie (signature on file)
H	Update manual to reduce the complexity of requirements. Changed the title from Quality Assurance Manual to Quality Management Manual. Added Zenith Mfg as a sister company.	QAM 1	04/07/08	Richard Marsh (signature on file)
H1	Quality Assurance Manager changed to Quality Manager. Reports to changed to President instead of Executive Management	QMM 5 5.5.2	06/13/08	Richard Marsh (Signature on File)

Section 1: Scope

1.1 General

Solara Engineering/Zenith Mfg./Zenith Mfg. is an aircraft Manufacturing & Technical Services firm located in Sun Valley, California and specializes in CNC Machining, Sheet Metal, Assembly, and Repair of Aerospace Parts and Components.

Manufacturing Solara Engineering/Zenith Mfg./Zenith Mfg. has 3, 4 & 5 Axis CNC milling capabilities capable of producing simple to complex parts. CNC turning capabilities to 3 axis of simple to complex parts. Assembly capabilities range from simple nutplate installations to main landing gear overhaul.

Sheet Metal operations are capable of spinning, bending, welding, punching, and shearing.

Technical Services provide engineering product support and documentation such as: 2D/3D modeling detail drawings (CATIA and Unigraphics), Assembly & Installation drawings, and Reverse Engineering.

The quality manual outlines the policies, procedures and requirements of the Quality Management System. The system is structured to comply with the conditions set forth in the International Standard SAE AS 9100 and customer requirements.

1.2 Application

All requirements of AS9100 are generic and are intended to be applicable to all organizations, regardless of type, size and product provided. This Quality Assurance Manual will be supplemented by procedures and instructions to define how the AS9100 standard will be applied.

Where any requirements of AS9100 cannot be applied due to the nature of Solara Engineering/Zenith Mfg./Zenith Mfg. and its product, this can be considered for exclusion.

In the event there is a conflict between a federal, state, local regulation or customer requirement and the Quality Assurance Manual and/or Quality Assurance Procedures, the federal, state, local regulation or customer requirement will take precedence.

Where exclusions are made, claims of conformity to AS9100 are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the Solara Engineering/Zenith Mfg./Zenith Mfg. ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

Exclusions

- 7.2.1 Determination of Requirements Related to the Product, post-delivery activities only – Solara Engineering/Zenith Mfg./Zenith Mfg. is a contract manufacturer and therefore does not perform any post-delivery activities, such as servicing.
- 7.3 Design and Development, inclusive of sub-clauses - Solara Engineering/Zenith Mfg./Zenith Mfg. is a contract manufacturer and therefore does not perform any design work.
- 7.5.1 Control of Production and Service Provision, service related and post-delivery requirements only – Solara Engineering/Zenith Mfg./Zenith Mfg. is a contract manufacturer and therefore does not provide service or post-delivery activities.
- 7.5.1.5 Control of Service Operations – Solara Engineering/Zenith Mfg./Zenith Mfg. is a contract manufacturer and therefore does not provide service activities.
- 7.5.2 Validation of Processes for Production and Service Provision, service related and special processes requirements only - Solara Engineering/Zenith Mfg./Zenith Mfg. is a contract manufacturer and therefore does not provide service activities or special processes.
- Addendum 1, 3.0 Variation Management in Design – Solara Engineering/Zenith Mfg. is a contract manufacturer and therefore does not perform any design work.

Section 2: Normative Reference

2.0 Quality Management System References

The following documents were used as reference during the preparation of the Quality Management System:

- American National Standard ANSI/AS 9001/ASQ Q9000-2000, Quality Management Systems - Vocabulary.
- American National Standard ANSI/AS 9001/ASQ Q9001-2000, Quality Management Systems – Requirements
- American National Standard ANSI/AS 9001/ASQ Q9004-2000, Quality Management Systems – Guidelines for performance Improvements
- Society of Automotive Engineers SAE AS 9100B - Quality Management Systems – Requirements
- Boeing BQMS standards
 - D6-82479 Revision B, Boeing Quality Management System Requirements for Supplier, Appendix A Addendum 1:AQS Continuous Improvement
 - D6-51991 Revision G, Quality Assurance Standard for Digital Product Definition at Boeing Suppliers
- Northrop Grumman standards
 - SQ&TP 0120 Northrop Grumman Supplier Quality Assurance Requirements (SQAR) Supplement for the Control and Use of Digital Datasets.
- AS9102 Aerospace First Article Inspection Requirement
- AS9103 Variation Management of Key Characteristics
- ISO10007 Configuration Management

Section 3: Definitions

3.0 Quality Management System Definitions

This section is for definitions unique to Solara Engineering/Zenith Mfg..

- Customer owned property - Any type of instrumentation, accessories, manuals, software, drawings, or documentation that belongs to a customer.
- Customer supplied product - Any type of service or material supplied to be utilized in the manufacture, modification or repair of customer-owned property.
- Executive Management – Managing Directors of the Company who possess ownership interest in the Company.
- Key Characteristics- The features of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or manufacturability. Same as Critical Characteristics.
- May 1. The term may is used when circumstances are not conclusive and / or Solara Engineering/Zenith Mfg. and / or customer is reserving the right to do so. 2. Permitted but not required. 3. Might
- Product – The end item result of meeting all contract terms and conditions (e.g.: manufactured goods, drawings, data, services etc.)
- Production Illustration (PI) - A technical process developed for the creation of drawings used in the support of a factory installation. It is a comparison or an example needed for explanation, corroboration, or documentation within a process flow.
- Quality Records – Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable.
- Top Management – Departmental Managers or above from Operations, Engineering, Manufacturing, Technical Services, Quality, etc.

Section 4

Quality Management System

4.1 General Requirements

Solara Engineering/Zenith Mfg. has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of AS 9100. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

To design and implement the QMS Solara Engineering/Zenith Mfg. has:

- Identified the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the Quality Assurance Manual;
- Determined the sequence and interaction of these processes, and illustrated them on the Process Flow Diagram;
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective, and documented them in quality plans, work instructions and the Measuring, Monitoring and Analysis Table;
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes;
- Established systems to monitor, measure and analyze these processes, and;
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes.

These processes will be managed by Solara Engineering/Zenith Mfg. Management in accordance with the requirements of AS9100.

Where Solara Engineering/Zenith Mfg. chooses to outsource any process that affects product conformity with requirements, Solara Engineering/Zenith Mfg. will ensure control over such processes. Control of such outsourced processes will be identified within the quality management system.

Note: Processes needed for the quality management system referred to above included processes for management activities, provision of resources, product realization and measurement.

4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

- A documented Quality Policy
- This Quality Manual
- Documented Procedures
- Work Instructions
- Documents identified as needed for the effective planning, operation and control of our processes, and
- Quality Records
- Records required by regulatory authorities.

Solara Engineering/Zenith Mfg. ensures that personnel have access to quality management system documentation and are aware of relevant procedures. We also provide customer or regulatory authorities' access to quality management system documentation.

Note: Where the term “documented procedure” appears within this Quality Assurance Manual, this means that the procedure is established, documented, implemented and maintained.

Note: The documentation can be in any form or type of medium.

4.2.2 Quality Manual

This Quality Manual has been prepared to describe Solara Engineering/Zenith Mfg.'s QMS. The scope and permissible exclusions of the QMS are described in section one of this manual. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section. The Process Flow Diagram at the end of section 4 provides a description of the interaction between the processes of the QMS system. The relationship between the AS 9100 standard and documented procedure has been indicated by use of a numbering system that correlates to the AS 9100 standard.

4.2.3 Control of Documents

All of the QMS documents are controlled according to the Document Control Procedure (4.2.4). This procedure defines the process for:

- Approving documents for adequacy prior to issue
- Reviewing and updating as necessary and re-approving documents
- Ensuring that changes and current revision status of documents are identified
- Ensuring that relevant versions of applicable documents are available at points of use
- Ensuring that documents remain legible and readily identifiable
- Ensuring that documents of external origin are identified and their distribution controlled
- Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose and
- Obtaining customer / regulatory agency approvals when required by contract or regulatory requirements
- Coordinating document changes with customers or regulatory authorities in accordance with contract or regulatory requirements.

4.2.4 Control of Quality Records

Records will be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management systems. Records will remain legible and readily identifiable and retrievable. A documented procedure will be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

The documented procedure will define the method for controlling records that are created by and / or retained by suppliers.

Records will be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

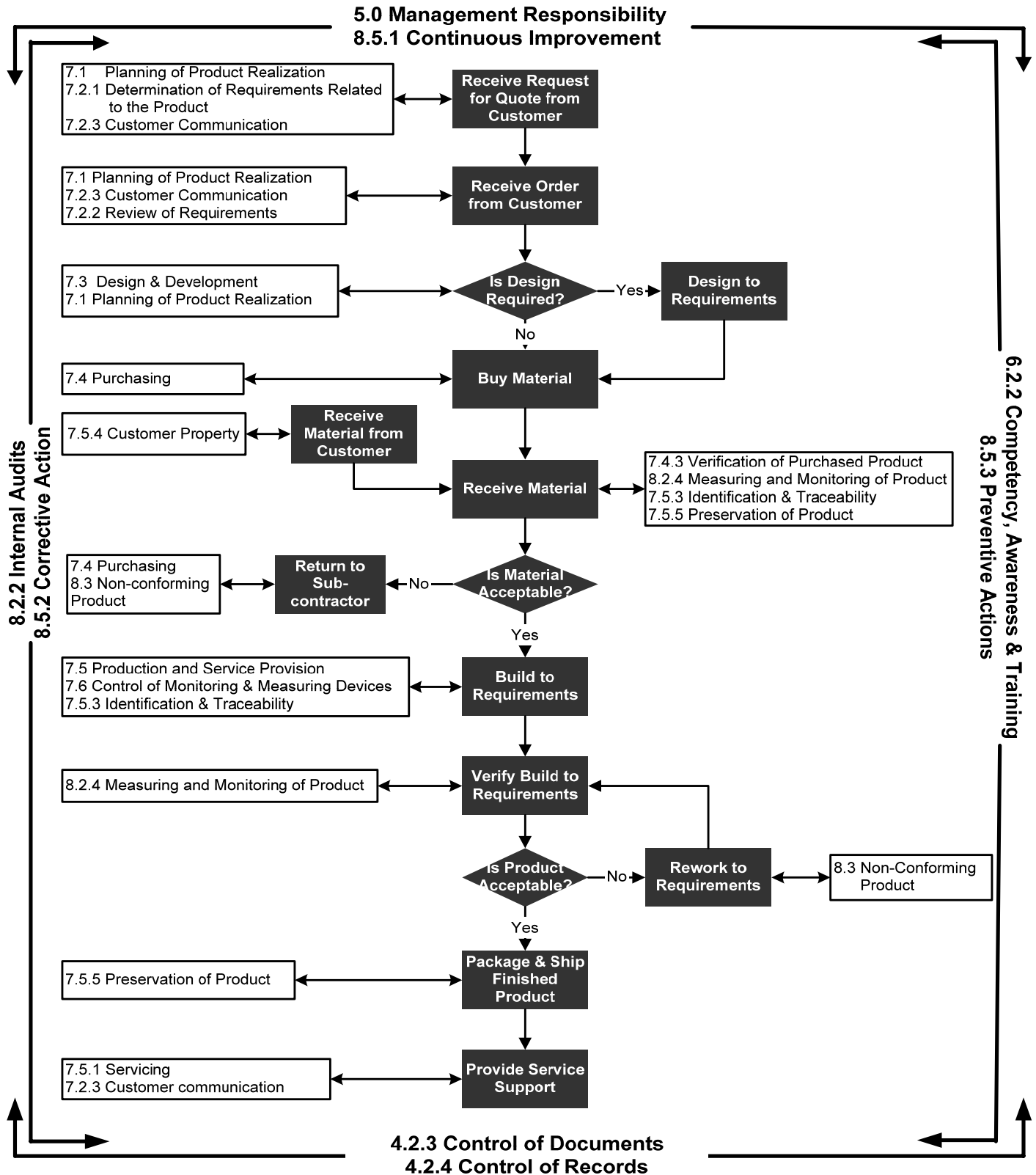
4.3 Configuration Management:

The organization has established, documented and maintains a configuration management process that is appropriate to the product.

Guidance on configuration management was gleaned from ISO 10007 as it was appropriate to Solara Engineering/Zenith Mfg.'s process.

Related Procedures

QMP 4	Quality Assurance Procedures Section 4
QAC 4.2.4 PRO	Interaction of Processes Chart



Section 5

Management Responsibility

5.1 Management Commitment

Top Management has been actively involved in implementing the quality management system (QMS). It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

To continue to provide leadership and show commitment to the improvement of the QMS, management will do the following:

- Communicate the importance of meeting customer, statutory, and regulatory requirements.
- Establish quality objectives
- Establish the quality policy.
- Conduct management reviews.
- Ensure the availability of resources.

5.2 Customer Focus

Solara Engineering/Zenith Mfg.. strives to identify current and future customer needs, to meet customer requirements and enhancing customer satisfaction.

Top Management ensures that customer requirements are understood and met, by requiring compliance with documented customer communication procedures. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people in our organization (see 7.2.1 and 8.2.1).

5.3 Quality Policy

The Quality Policy is appropriate for the purposes of Solara Engineering/Zenith Mfg.. and includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system.

Top Management ensures that the quality policy is communicated to all employees. It is included in new employee training and training on the QMS.

Management reviews the quality policy annually to determine the policy's continuing suitability for our organization.

5.4 Planning

5.4.1 Quality Objectives

Top management will ensure that quality objectives, including those needed to meet requirements for product (see 7.1a), are established at relevant functions and levels within Solara Engineering/Zenith Mfg.. The quality objectives will be measured and consistent with the quality policy.

5.4.2 Quality Management System Planning

The quality system has been planned and implemented to meet our quality objectives and the requirements of 4.1 of the AS 9100 standard as well as the quality objectives. Quality planning takes place as changes that affect the quality system are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility Accountability and Authority

Organizational charts have been established to show the interrelation of personnel in the organization. Job functions define the responsibilities and authorities of the positions in the Company, and which are reviewed and approved by top management for adequacy. A management organizational chart is located in the Organizational Structure section of this manual.

5.5.2 Management Representative

The **Quality Manager** has been appointed by Executive Management as management representative. As management representative, he has the following responsibility and authority:

- Ensure that processes needed for the quality management system are established and implemented.
- Report to the **President** on the performance of the quality management system, and note needed improvements.
- Promote awareness of customer requirements throughout the organization.
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS and
- Over see matters pertaining to quality issues
- Organizational freedom to resolve matters pertaining to quality.

5.5.3 Internal Communication

Top management will ensure that appropriate communication processes are established and that communication takes place regarding the effectiveness of the quality management system.

Methods of communicating the effectiveness of the QMS include department and management meetings, management review, circulation of minutes of management review meetings, internal audit closing meetings, employee communications board, and other routine business communication.

Employees can communicate their ideas and concerns through an open door policy with management at all levels or through a suggestion box if they wish to remain anonymous.

5.6 Management review

5.6.1 General

Executive and Top Management review the QMS at management review meetings. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting. (see 4.2.4)

The number and frequency of the management review meetings will be at management's discretion. The entire QMS system must be reviewed annually.

5.6.2 Review Input

Assessment of the QMS is based on a review of information inputs to management review. These inputs include the following:

- a. Results of audits
- b. Customer feedback
- c. Process performance and product conformity
- d. Company level quality data
- e. Status of preventive and corrective actions
- f. Follow-up actions from previous management reviews
- g. Planned changes that could affect the quality management system
- h. Recommendations for improvement

5.6.3 Review Output

During these review meetings, management will identify appropriate actions to be taken regarding the following issues:

- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Resource needs

Responsibility for required actions is assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of management review.

References

QMP 5 – Quality Assurance Procedures Section 5

Section 6

Resource Management

6.1 Provision of Resources

Solara Engineering/Zenith Mfg. has implemented a Quality Management System that complies with the AS 9100 standard. This implementation was achieved with management commitment and with sufficient resources for the implementation. To effectively maintain and continually improve the system, management determines and provides necessary resources.

Solara Engineering/Zenith Mfg. will determine and provide resources needed to enhance customer satisfaction by meeting customer requirements.

6.2 Human Resources

6.2.1 General

Personnel performing work affecting product quality will be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, Awareness and Training

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. Human Resources will maintain records of employee qualifications. Department Managers will prepare a Skills and Competency Report at least annually for each employee. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job. The results are then evaluated to determine if they were effective.

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

6.3 Infrastructure

To meet quality objectives and product requirements Solara Engineering/Zenith Mfg. has determined the infrastructure needed. The infrastructure has been provided, and includes buildings, workspace, utilities, process equipment and supporting services. As new infrastructure requirements arise, they will be documented in quality plans. Existing infrastructure is maintained to ensure product conformity.

6.4 Work Environment

A work environment suitable for achieving product conformance is maintained. Requirements are determined during quality planning and documented in the quality plan. The work environment is managed for continuing suitability. Data from the quality system is evaluated to determine if the work environment is

Quality Management Manual

sufficient for achieving product conformance, or if preventive or corrective action related to the work environment is required.

Note: Factors monitored that may affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.

References

QMP 6 – Quality Assurance Procedures Section 6

Section 7

Product Realization

7.1 Planning of Product Realization

Solara Engineering/Zenith Mfg. will plan and develop the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, Solara Engineering/Zenith Mfg. will determine the following, as appropriate:

- a. Quality objectives and requirements for the product;
- b. The need to establish processes, documents and provide resources specific to the product;
- c. Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
- d. Records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4);
- e. The identification of resources to support operation and maintenance of the product.

The output of this planning is in a form suitable for Solara Engineering/Zenith Mfg.'s method of operations.

Note: A document specifying the processes of the quality management system (including product realization processes) and the resources to be applied to a specific product, project, or contract, can be referred to as a quality plan.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

Solara Engineering/Zenith Mfg. determines customer requirements before acceptance of an order. Customer requirements include those:

- Requested by the customer
- Required for delivery and post-delivery activities
- Not stated by the customer but necessary for specified use or known and intended use
- Statutory and regulatory requirements related to the product
- Additional requirements determined by Solara Engineering/Zenith Mfg.

7.2.2 Review of Requirements Related to the Product

Solara Engineering/Zenith Mfg. will review the requirements related to the product. This review will be conducted prior to Solara Engineering/Zenith Mfg.'s commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and will ensure that:

- a. Product requirements are defined,
- b. Contract or order requirements differing from those previously expressed are resolved,
- c. Solara Engineering/Zenith Mfg. has the ability to meet the defined requirements, and
- d. Risks (e.g. new technology, short delivery time scale) have been evaluated.

Records of the results of the review and actions arising from the review will be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements will be confirmed by Solara Engineering/Zenith Mfg. before acceptance.

Where product requirements are changed, Solara Engineering/Zenith Mfg. will ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Customer Communication

Solara Engineering/Zenith Mfg. will determine and implement effective arrangements for communicating with customers in relation to:

- Product Information
- Enquiries, contracts and order handling, including amendments
- Customer Feedback, including customer complaints
- Service Support as defined by customer requirements

7.3 Design and Development

Solara Engineering/Zenith Mfg. is not involved in design and development of any propriety products.

7.4 Purchasing

7.4.1 Purchasing Process

Solara Engineering/Zenith Mfg. will ensure that purchased product conforms to the specified purchased requirements. The type and extent of control applied to the supplier and the purchased product will be dependent upon the effect of the purchased product on subsequent product realization or the final product.

Solara Engineering/Zenith Mfg. will be responsible for the quality of all products purchased from suppliers, including customer-designated sources.

Solara Engineering/Zenith Mfg. will evaluate and select suppliers based on their ability to supply product in accordance with Solara Engineering/Zenith Mfg.'s requirements. Criteria for selection, evaluation and re-evaluation will be established. Records of the results of evaluations and any necessary actions arising from the evaluation will be maintained (see 44.2.4).

Solara Engineering/Zenith Mfg. will:

- a. Maintain a register of approved suppliers that includes the scope of the approval;
- b. Periodically review supplier performance; records of these reviews will be used as a basis for establishing the level of controls to be implemented;
- c. Define the necessary actions to take when dealing with suppliers that do not meet requirements;
- d. Ensure where required that both Solara Engineering/Zenith Mfg. and all suppliers use customer-approved special process sources;
- e. Ensure that the function having responsibility for approving supplier quality systems has the authority to disapprove the use of sources.

7.4.2 Purchasing Information

Purchasing information will describe 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. Quality management system requirements,
- d. The name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data,
- e. Requirements for design, test, examination, inspection and related instructions for acceptance by Solara Engineering/Zenith Mfg.,
- f. Requirements for test specimens (e.g. production method, number, storage conditions) for design approval, inspection, investigation or auditing,
- g. Requirements relative to:
 - Supplier notification to Solara Engineering/Zenith Mfg. of nonconforming

- product and
- Arrangements for Solara Engineering/Zenith Mfg.'s approval of supplier nonconforming material,
 - h. Requirements for supplier to notify Solara Engineering/Zenith Mfg. of changes in product and / or process definition and, where required, obtain Solara Engineering/Zenith Mfg. / Customer / Government approval,
 - i. Right of access by Solara Engineering/Zenith Mfg., their customer, and regulatory authorities to all facilities involved in the order and to all applicable records, and
 - j. Requirements for supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.

Solara Engineering/Zenith Mfg. will ensure the adequacy of specified purchase requirements prior to their communication to suppliers.

7.4.3 Verification of Purchased Product

Solara Engineering/Zenith Mfg. will establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Verification activities may include:

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

Purchased product will not be used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure.

Where Solara Engineering/Zenith Mfg. utilizes test reports to verify purchased product, the data in those reports will be acceptable per applicable specifications. Solara Engineering/Zenith Mfg. will periodically validate test reports for raw material.

Where Solara Engineering/Zenith Mfg. delegates verification activities to the supplier, the requirements for delegation will be defined and a register of delegations maintained.

Where Solara Engineering/Zenith Mfg. or its customer intends to perform verification at the supplier's premises, Solara Engineering/Zenith Mfg. will state the intended verification arrangements and method of product release in the

purchasing information.

Where specified in the contract, the customer or the customer's representative will be afforded the right to verify at the supplier's premises and Solara Engineering/Zenith Mfg.'s premises that subcontracted product conforms to specified requirements.

Verification by the customer will not be used by Solara Engineering/Zenith Mfg. as evidence of effective control of quality by the supplier and will not absolve Solara Engineering/Zenith Mfg. of the responsibility to provide acceptable product, nor will it preclude subsequent rejection by the customer.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Exclusion: Service related and post-delivery activities.

Planning will consider, as applicable:

- a. The establishment of process controls and development of control plans where key characteristics have been identified,
- b. The identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization,
- c. The design, manufacture and use of tooling so that variable measurements can be taken, particularly key characteristics, and
- d. Special processes (see 7.5.2).

Solara Engineering/Zenith Mfg. will plan and carry out production and service provision under controlled conditions. Controlled conditions will include as applicable:

- a. The availability of information that describes the characteristics of the product,
- b. The availability of work instructions, as necessary,
- c. The use of suitable equipment,
- d. The availability and use of monitoring and measuring devices,
- e. The implementation of monitoring and measurement,
- f. The implementation of release, delivery and post-delivery activities,
- g. Accountability for all product during manufacture (e.g. parts quantities, split orders, nonconforming product),
- h. Evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized,
- i. Provision for the 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 that they affect product quality, and
- k. Criteria for workmanship, which will be stipulated in the clearest practical manner (e.g. written standards, representative samples or illustrations).

7.5.1.1 Production Documentation

Production operations are carried out in accordance with approved data. This data contains as necessary:

- Drawings, parts lists, process flow charts including inspection operations, production documents and inspection documents
- A list of specific or non-specific tools and numerical control (NC) machine programs required and specific instructions associated with their use.

7.5.1.2 Control of Production Process Changes:

Persons authorized to approve changes to production processes will be identified.

Solara Engineering/Zenith Mfg. will identify and obtain acceptance of changes that require customer and / or regulatory authority approval in accordance with contract or regulatory requirements.

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

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

7.5.1.3 Control of Production Equipment, Tools and Numerical Control (NC) Machine Programs

Production equipment, tools and programs are validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use includes verification of the first article produced to the design data/specification. Storage requirements, including periodic preservation/condition checks, have been established for production equipment or tooling in storage.

7.5.1.4 Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities

When planning to temporarily transfer work to a location outside the organization's facilities, the organization defines the process to control and validate the quality of the work.

7.5.1.5 Control of Service Operations

Exclusion: Service related activities.

7.5.2 Validation of Processes for Production and Service Provision

Exclusion: Service related activities and special processes.

Solara Engineering/Zenith Mfg. will validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies became apparent only after the product is in use or the service has been delivered.

Note: These processes are frequently referred to as special processes. Solara Engineering/Zenith Mfg. performs no Special Processes at this time. These protocols will be followed as applicable to contract requirements.

Validation will demonstrate the ability of these processes to achieve planned results.

Solara Engineering/Zenith Mfg. will establish arrangements for these processes including, as applicable:

- a. Defined criteria for review and approval of the processes,
 - Qualifications and approval of special processes prior to use,
- b. Approval of equipment and qualification of personnel,
- c. Use of specific methods and procedures,
 - Control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto,
- d. Requirements for records (see 4.2.4), and
- e. Revalidation.

7.5.3 Identification and Traceability

Where appropriate, Solara Engineering/Zenith Mfg. will identify the product by suitable means throughout product realization.

Solara Engineering/Zenith Mfg. will maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

Solara Engineering/Zenith Mfg. will identify the product status with respect to monitoring and measurement requirements.

Where acceptance authority media is used (e.g. stamps, electronic signatures, passwords), Solara Engineering/Zenith Mfg. will establish and document controls for the media.

Where traceability is a requirement, Solara Engineering/Zenith Mfg. will control and record the unique identification of the product (see 4.2.4)

According to the level of traceability required by contract, regulatory, or other established requirements, **Solara Engineering/Zenith Mfg.'s system will provide for:**

- a. Identification to be maintained throughout the product life;
- b. All the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch;
- c. For an assembly, the identity of its components and those of the next higher

- assembly to be traced;
- d. For a given product, sequential records of its production (manufacture, assembly, inspection) to be retrieved.

7.5.4 Customer Property

Solara Engineering/Zenith Mfg. will exercise care with customer property while it is under Solara Engineering/Zenith Mfg.'s control or being used by Solara Engineering/Zenith Mfg.. Solara Engineering/Zenith Mfg. will identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this will be reported to the customer and records maintained (see 4.2.4).

Note: Customer property can include intellectual property, including customer furnished data used for design, production and / or inspection.

7.5.5 Preservation of Product

Solara Engineering/Zenith Mfg. will preserve the conformity of product during internal processing and delivery to the intended destination. This preservation will include identification, handling, packaging, storage and protection. Preservation will also apply to the constituent parts of a product.

Preservation of product will also include, where applicable in accordance with product specifications and / or applicable regulations, provisions for:

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

Solara Engineering/Zenith Mfg. will ensure that documents required by the contract / order to accompany the product are present at delivery and are protected against loss and deterioration.

7.6 Control of Monitoring and Measuring Devices

Solara Engineering/Zenith Mfg. will determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

Solara Engineering/Zenith Mfg. will maintain a register of these monitoring and measuring devices, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

Note: Monitoring and measuring devices include, but are not limited to: test

hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.

Solara Engineering/Zenith Mfg. will establish processes to ensure that monitoring and measurement can be carried out and are carried in a manner that is consistent with monitoring and measurement requirements.

Solara Engineering/Zenith Mfg. will ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

Where necessary to ensure valid results, measuring equipment will:

- a. Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national standards; where no such standards exist, the basis used for calibration or verification will be recorded;
- b. Be adjusted or re-adjusted as necessary;
- c. Be identified to enable the calibration status to be determined;
- d. Be safeguarded from adjustments that would invalidate the measurement result;
- e. Be protected from damage and deterioration during handling, maintenance and storage;
- f. Be recalled to a defined method when requiring calibration.

In addition, Solara Engineering/Zenith Mfg. will assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. Solara Engineering/Zenith Mfg. will take appropriate actions on the equipment and any product affected. Records of the results of calibration and verification will be maintained (see 4.2.4).

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

ISO 10012-1 and ISO 10012-2 may be used for guidance.

References

QMP 7 – Quality Assurance Procedures Section 7

Section 8

Measurement, Analysis and Improvement

8.1 General

Solara Engineering/Zenith Mfg. will plan and implement the monitoring, measurement, analysis and improvement processes needed:

- a. To demonstrate conformity of the product,
- b. To ensure conformity of the quality management system, and
- c. To continually improve the effectiveness of the quality management system.

This will include determination of applicable methods, including statistical techniques and the extent of their use.

Note: According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support:

- a. Design verification (e.g. reliability, maintainability, safety);
- b. Process control;
 - Selection and inspection of key characteristics;
 - Process capability measurements;
 - Statistical process control;
 - Design of experiment;
- c. Inspection – matching sampling rate to the criticality of the product and to the process capability;
- d. Failure mode and effect analysis.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, Solara Engineering/Zenith Mfg. will monitor information relating to customer perception as to whether Solara Engineering/Zenith Mfg. has met customer requirements. The methods for obtaining and using this information will be determined

8.2.2 Internal Audit

Solara Engineering/Zenith Mfg. conducts internal audits at planned intervals to determine whether the quality management system

- Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization
- Is effectively implemented and maintained.

An audit program has been designed and implemented and identifies an audit schedule based on the importance of the areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, methods,

responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, will be defined.

Auditors will not audit their own work.

The management responsible for the area being audited is responsible for ensuring that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

Follow-up activities will include the verification of the actions taken and the reporting of the verification results (see 8.5.2).

Detailed tools and techniques will be developed such as checksheets, process flowcharts, or any similar method to support audit of the quality management system requirements. The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall organization performance.

Internal audits meet contract and/or regulatory requirements.

8.2.3 Monitoring and Measurement of Processes

Solara Engineering/Zenith Mfg. applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product. In the event of process nonconformity, the organization:

- Takes appropriate action to correct the nonconforming process,
- Evaluates whether the process nonconformity has resulted in product nonconformity, and
- Identifies and controls the nonconforming product in accordance with clause 8.3.

8.2.4 Monitoring and Measurement of Product

Solara Engineering/Zenith Mfg. will monitor and measure the characteristics of the product to verify that product requirements have been met. This will be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).

When key characteristics have been identified, they will be monitored and controlled.

When Solara Engineering/Zenith Mfg. uses sampling inspection as a means of product acceptance, the plan will be statistically valid and appropriate for use. The plan will

preclude the acceptance of lots whose samples have known nonconformities. When required, the plan will be submitted for customer approval.

Product will not be used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities.

Evidence of conformity with the acceptance criteria will be maintained. Records will indicate the persons(s) authorizing release of product (see 4.2.4).

Product release and service delivery will not proceed until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and where applicable, by customer.

8.2.4.1 Inspection Documentation

Measurement requirements for product or service acceptance are documented. This documentation is part of the production documentation, and includes:

- Criteria for acceptance and/or rejection,
- Where in the sequence measurement and testing operations are performed,
- A record of the measurement results, and
- Type of measurement instruments required and any specific instructions associated with their use.
- Test records shall show actual test results data when required by specification or acceptance test plan.
- Where required to demonstrate product qualification the organization shall ensure that records provide evidence that the product meets the defined requirements.

8.2.4.2 First Article Inspection

The organization's 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.

AS 9102 will be used for guidance.

8.3 Control of Nonconforming Product

Solara Engineering/Zenith Mfg. will ensure that product which 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 will be defined in a documented procedure.

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

Solara Engineering/Zenith Mfg.’s documented procedure will define the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions.

Solara Engineering/Zenith Mfg. will deal with nonconforming product by one of more of the following ways:

- a. By taking action to eliminate the detected nonconformity;
- b. By authorizing its use, release or acceptance under concession by a relevant authority and where applicable, by the customer;
- c. By taking action to preclude its original intended use or application.

Solara Engineering/Zenith Mfg. will not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if:

- a. The product is produced to customer design, or
- b. The nonconformity results in a departure from the contract requirements.

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

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, will be maintained (see 4.2.4).

When nonconforming product is corrected it will be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, Solara Engineering/Zenith Mfg. will take action appropriate to the effects, or potential effects, of the nonconformity.

In addition to any contract or regulatory authority reporting requirements, Solara Engineering/Zenith Mfg.’s system will provide for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification will include a clear description of the nonconformity, which includes as necessary parts affected, customer and / or organization part numbers, quantity and date(s) delivered.

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

8.4 Analysis of Data

Solara Engineering/Zenith Mfg. determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management

system can be made. Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

- Customer satisfaction
- Conformance to product requirements
- Characteristics and trends of processes and products including opportunities for preventive action
- Suppliers

8.5 Improvement

8.5.1 Continual Improvement

Solara Engineering/Zenith Mfg. continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective Action

Solara Engineering/Zenith Mfg. takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure (QMP Section 8) defines requirements for

- Reviewing nonconformities (including customer complaints),
- Determining the causes of nonconformities,
- Evaluating the need for action to ensure that nonconformities do not recur,
- Determining and implementing action needed,
- Records of the results of action taken (see 4.2.4), and
- Reviewing corrective action taken.
- Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause, and specific actions where timely and/or effective corrective actions are not achieved.

8.5.3 Preventive Action

Solara Engineering/Zenith Mfg. determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure (QMP Section 8) defines requirements for:

- Determining potential nonconformities and their causes
- Evaluating the need for action to prevent occurrence of nonconformities
- Determining and implementing action needed
- Records of results of action taken
- Reviewing preventive action taken

References

QMP 8 – Quality Assurance Procedures Section 8