

# Plasma Ruggedized Solutions



## AS9100B Quality System Manual

## Quality Policy

Plasma Ruggedized Solutions is focused on our customer's ultimate success, and is committed to pursuing the highest level of quality in the Conformal Coating industry. The guiding principle of Plasma Ruggedized Solutions is to provide our customers, both external and internal, with a level of quality and service that consistently meets or exceeds expectations. Plasma Ruggedized Solutions embraces the following philosophies:

- ◆ Plasma Ruggedized Solutions will continually improve the effectiveness of our Quality Management System (QMS).
- ◆ We will provide exceptional customer service.
- ◆ We will practice effective communication of the quality policy and objectives to customers, suppliers and our employees.
- ◆ It is the responsibility of every Plasma Ruggedized Solutions employee to help achieve the best practices within our industry to profitably promote organizational growth.
- ◆ Plasma Ruggedized Solutions management will exercise employee empowerment and development at all levels.

## Scope of Registration

Conformal Coating, Encapsulation and Potting of Printed Circuit Boards.

## Exclusions and Justifications

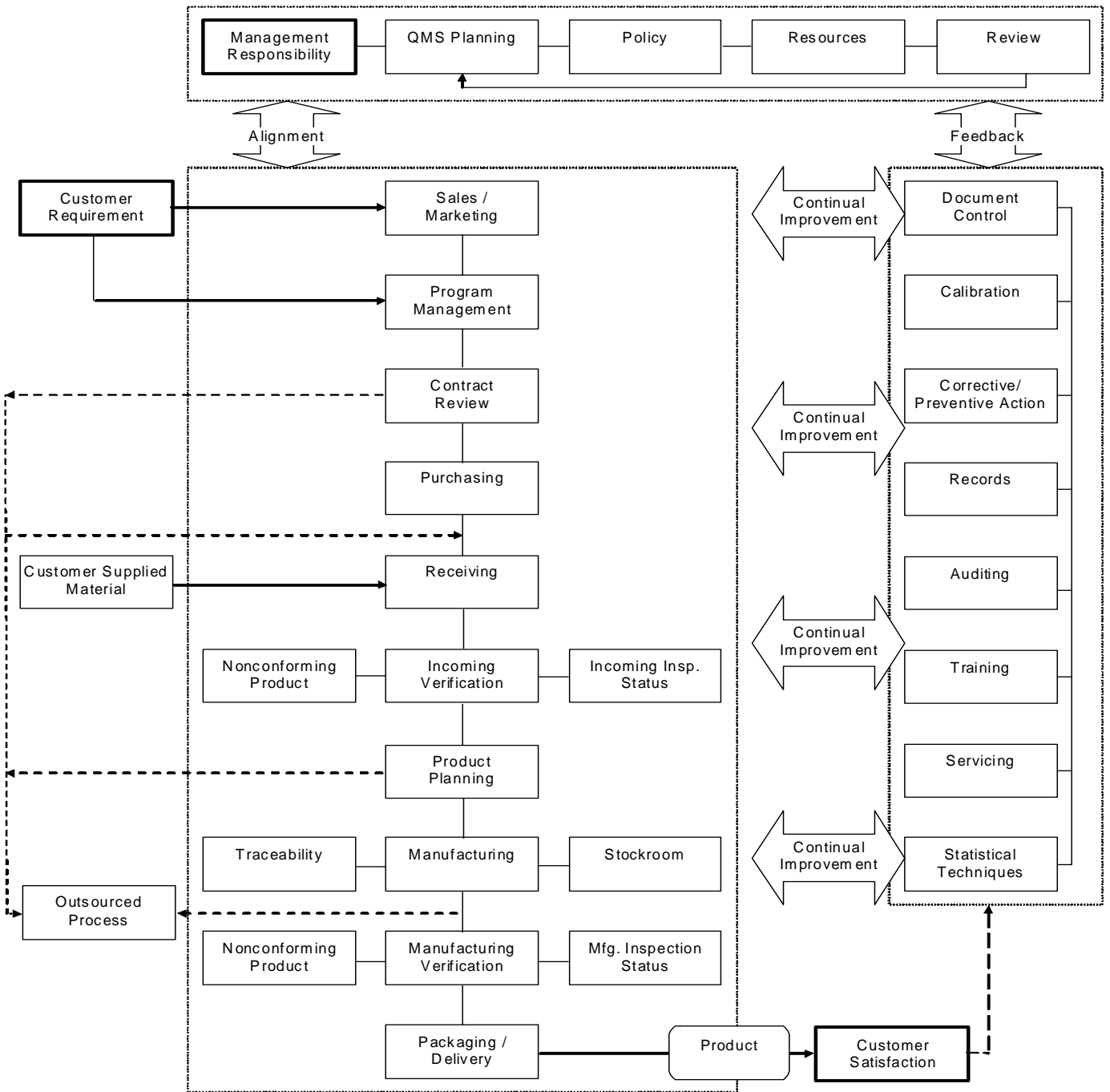
Clauses 7.3, Design, 7.5.1.5, Control of Service Operations, and 7.5.2 Validation of Processes for Production and Service Provision are excluded. PRS does not perform design. PRS does not service its product other than internal warranty repairs. Special processes are not performed, as all product specifications are inspected and verified.

Clauses 7.4.1 Purchasing Process, and 7.4.2 Purchasing Information does not apply to Huntington Beach, CA. San Jose does Purchasing.

**Note:** This quality manual is written to specifically follow the AS9100B/ISO 9001:2008 standards in order to clearly demonstrate intent, provide subsequent ease in auditing, and minimize necessary revisions of the quality manual. Additional requirements and references to more frequently revised subordinate documents, procedures, work instructions, forms, records, drawings, etc., as applicable, are identified in italics.

**Note:** For ease of reference and assurance of conforming to minimal requirements, ISO 9001:2008 requirements for documents or records are bolded and italicized.

## Interaction Between Processes



## 4.0 QUALITY MANAGEMENT SYSTEM

### 4.1 Quality System – General Requirements

PRS shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of AS9100B/ISO9001:2008, and shall:

- a) Determine processes needed for the quality management system and their application throughout the company,
- b) Determine the sequence and interaction of these processes,
- c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) Monitor, measure where applicable, and analyze these processes, and
- f) Implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed in accordance with AS9100B/ISO 9001:2008. Outsourced processes affecting conformity shall be controlled and shall be identified within the quality management system. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

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

### 4.2 Documentation Requirements

#### 4.2.1 General

The quality management system documentation shall include:

- a) **Documented statements of a quality policy and quality objectives,**
- b) A quality manual,
- c) **Documented procedures and records required by AS9100B/ ISO 9001:2008 (see 4.2.4),**
- d) Documents needed to ensure the effective planning, operation and control of processes, and
- e) Quality system requirements imposed by applicable regulatory authorities.

Personnel shall have access to quality management system documentation and be aware of relevant procedures. Customer and/or regulatory authorities representatives shall have access to quality management system documentation.

Note 1: The documented procedure is established, documented, implemented and maintained.

Note 2: The extent of the quality management system documentation differs due to:

- a) The size and type of activities
- b) The complexity of processes and their interactions, and
- c) The competence of personnel

Note 3: The documentation can be in any form or type of medium.

#### 4.2.2 Quality Manual (QM)

PRS shall establish and maintain a quality manual that includes

- a) The scope of the quality management system, including details of and justification for any exclusions,

- b) The **documented procedures established for the quality management system, or reference to them**, and when referencing the documented procedures, the relationship between the requirements of this international standard and the documented procedures shall be clearly shown; and
- c) A description of the interactions between the processes of the quality management system.

#### 4.2.3 Control of Documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements of given in 4.2.4. A **documented procedure shall be established** to define the controls needed

- a) To approve documents for adequacy prior to issue,
- b) To review and update as necessary and re-approve documents,
- c) To ensure that changes and the current revision status of documents are identified,
- d) To ensure that relevant versions of the applicable documents are available at points of use,
- e) To ensure that documents remain legible and readily identifiable,
- f) To ensure that documents of external origin determined to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
- g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The organization shall coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

*Refer to WI-42-1, Control of Documents and Records. WI-42-1 lists all procedures and records, each numbered according to their relevant AS9100 clause, thereby fulfilling the requirements of AS9100 4.2.2b.*

#### 4.2.4 Control of Quality Records

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

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

The records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

*Refer to WI-42-1, Control of Documents and Records.*

#### 4.3 Configuration Management

Configuration management processes consist of documenting customer requirements for each particular job, and are established, documented and maintained within the customer requirements and product realization processes.

*Refer to WI-71-7, Travelers.*

### 5.0 MANAGEMENT RESPONSIBILITY

#### 5.1 Management Commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

- a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

- b) Establishing the quality policy,
- c) Ensuring that quality objectives are established,
- d) Conducting management reviews, and
- e) Ensuring the availability of resources.

## **5.2 Customer Focus**

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.1 and 8.2.1).

## **5.3 Quality Policy**

Top management shall ensure that the quality policy

- a) Is appropriate to the purpose of the company,
- b) Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
- c) Provides a framework for establishing and reviewing quality objectives, is communicated and understood within the organization, and
- d) Is reviewed for continuing suitability.

## **5.4 Planning**

### **5.4.1 Quality Objectives**

Top management shall ensure that quality objectives, including those needed to meet requirements for product (see 7.1a), are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

*Refer to WI-002, Quality Objectives, shall be posted in area(s) accessible and frequented by all employees.*

### **5.4.2 Quality Management System Planning**

Top management shall ensure that

- a) The planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
- b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

## **5.5 Responsibility, Authority and Communication**

### **5.5.1 Responsibility and Authority**

Top management shall ensure that responsibilities and authorities are defined and communicated within the company.

*Refer to F-56-2, Organizational Chart.*

### **5.5.2 Management Representative**

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes

- a) Ensuring that processes needed for the quality management system are established, implemented and maintained,
- b) Reporting to top management on the performance of the quality management system and any need for improvement, and
- c) Ensuring the promotion of awareness of customer requirements throughout the company and
- d) The organizational freedom to resolve matters pertaining to quality.

Note: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management systems.

### **5.5.3 Internal Communication**

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

## **5.6 Management Review**

### **5.6.1 General**

Top management shall review the company's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

**Records from management reviews shall be maintained** (see 4.2.4).

*Management shall complete a full review the organization's Quality Management System on an annual basis to coincide with the completion of the annual Internal Quality Audit. As a minimum, the General Manager, Quality Manager/Management Representative, and the Operation Manager shall participate in the review process. The President, an invitee to the Management Review Meeting, at his own discretion, may or may not attend the review process and, may or may not provide an input or change to the conclusion of the review process. Employee participation is encouraged to facilitate broader input. The purpose of this review is to ensure its continuing suitability, adequacy, and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Form 56-01, Management Review Record, shall be used and maintained as a record of management reviews.*

### **5.6.2 Review Input**

The input to management review shall include information on:

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

### **5.6.3 Review Output**

The output from the management review shall include any decisions and actions related to:

- a) Improvement of the effectiveness of the quality management system and its processes;
- b) Improvement of product related to customer requirements, and
- c) Resource needs.

## **6.0 Resource Management**

### **6.1 Provision of Resources**

The company shall determine and provide the resources needed

- a) To implement and maintain the quality management system and continually improve its effectiveness, and
- b) To enhance customer satisfaction by meeting customer requirements.

## **6.2 Human Resources**

### **6.2.1 General**

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

### **6.2.2 Competence, Training and Awareness**

The company shall

- a) Determine the necessary competence for personnel performing work affecting product requirements,
- b) Where applicable, provide training or take other actions to achieve the necessary competence,
- c) Evaluate the effectiveness of the actions taken,
- d) Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- e) Maintain **appropriate records** of education, training, skills and experience (see 4.2.4).

*Refer to WI-62-1, Training.*

## **6.3 Infrastructure**

The company shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable,

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

*Form 63-1, Preventive Maintenance Record, shall constitute a record of preventive maintenance performed on that affecting product realization, as applicable.*

## **6.4 Work Environment**

The company shall determine and manage the work environment needed to achieve conformity to product requirements.

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

*Refer to WI-71-3, ESD Control System.*

## **7.0 Product Realization**

### **7.1 Planning of Product Realization**

The company shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the company shall determine the following, as appropriate:

- a) Quality objectives and requirements for the product;

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- b) The need to establish processes and documents, and to provide resources specific to the product;
- c) Required verification, validation, monitoring, measurement, 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.
- e) The identification of resources to support operation and maintenance of the product.

The output of this planning shall be in the form suitable for the company's method of operations.

Note 1: A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

*All documents, work instructions, drawings, and forms relevant to product realization are identified in WI-42-1, Control of Documents and Records.*

## **7.2 Customer Related Processes**

### **7.2.1 Determination of Requirements Related to the Product**

The company shall determine

- a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities,
- b) Requirements not stated by the customer but necessary for specified or intended use, where known,
- c) Statutory and regulatory requirements applicable to the product,
- d) Any additional requirements considered necessary by the company, and

*Form 72-2, Quote Worksheet shall be used to identify customer requirements prior to completing Form 72-3, Quote for submission to customers. For new customer part numbers for which a traveler is not on file, Form 72-4, New Traveler Engineering Worksheet shall be used in lieu of Form 72-2.*

### **7.2.2 Review of Requirements Related to the Product**

The company shall review the requirements related to the product. This review shall be conducted prior to the company'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 shall ensure that

- a) Product requirements are defined,
- b) Contract or order requirements differing from those previously expressed are resolved,
- c) The company 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 shall be maintained*** (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

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

### **7.2.3 Customer Communication**

The company shall determine and implement effective arrangements for communicating with customers in relation to

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

### **7.3. Design and Development**

Excluded.

### **7.4. Purchasing**

#### **7.4.1 Purchasing Process**

The company shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on the subsequent product realization or the final product.

The company shall be responsible for the quality of all products purchased from suppliers, including customer-designated sources.

The company shall evaluate and select suppliers based on their ability to supply product in accordance with the company's requirements. Criteria for selection, evaluation and re-evaluation shall be established. **Record of the results of evaluations and any necessary actions arising from the evaluation shall be maintained** (see 4.2.4).

The company shall:

- a) **Maintain a register of approved suppliers that includes the scope of approval;**
- b) Periodically review supplier performance; **records of these reviews shall 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 requirement;
- d) Ensure where required that both the company and all suppliers use customer-approved special process sources; and
- 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 shall 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 the company,
- f) Requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing,
- g) Requirements relative to
  - a. Supplier notification to the company of nonconforming product, and
  - b. Arrangements for the company to approve supplier nonconforming material,
- h) Requirements for the supplier to notify the company of changes in product and/or process definition and, where required, obtain the company approval,

- i) Right of access by the organization, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records, and
- j) Requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.

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

### **7.4.3 Verification of Purchased Product**

The company shall 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 (i.e., 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 the supplier, or supplier certification.

Purchased product shall not be used or processed until had been verified as conforming to specified requirements. Releasing purchased product until such time under positive recall procedures is not allowed.

Where the company uses test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. The company shall periodically validate test reports for raw material.

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

Where the company or its customer intends to perform verification at the supplier's premises, the company shall 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 shall be afforded the right to verify at the supplier's premises and the company's premises that subcontracted product conforms to specified requirements.

Verification by the customer shall not be used by the company as evidence of effective control of quality by the supplier and shall not absolve the company of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

*Refer to WI-74-1, Purchasing.*

## **7.5 Production and Service Provision**

### **7.5.1 Control of Production and Service Provision:**

Planning shall consider, as applicable,

- The establishment of process controls and development of control plans where key characteristics have been identified
- The identification of in-process verification points when adequate verification of conformance cannot be performed at a later state of realization,

- The design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and
- Special processes.

The company shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall 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 equipment,
- e) The implementation of monitoring and measure,
- f) The implementation of product 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 they affect product quality, and
- k) Criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g, written standards, representative samples, or illustrations).

#### **7.5.1.1 Production Documentation:**

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

- a) Drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents, and
- b) A list of specific or non-specific tools and numerical control (NC) machine programs required and any specific instructions associated with their use.

#### **7.5.1.2 Control of Production Process Changes**

*Quality Manager to approve changes to production processes shall be identified.*

The company shall 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 shall be documented. Procedures shall be available to control their implementation.***

The results of changes to production processes shall 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 shall be validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use shall include verification of the first article produced to design data/specification.***

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

#### **7.5.1.4 Control of Work Transferred, on a Temporary Basis, Outside the Company's Facilities:**

When planning to temporarily transfer work to a location outside the company's facilities, the company shall define the process to control and validate the quality of work. This shall be accomplished through normal purchasing and receipt inspection activities.

#### **7.5.1.5 Control of Service Operations**

Excluded

#### **7.5.2 Validation of Processes for Production and Service Provision**

Excluded.

#### **7.5.3 Identification and Traceability**

Where appropriate, the company shall identify the product by suitable means throughout product realization.

The company shall maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

The company shall identify the product status with respect to monitoring and measurement requirements throughout product realization.

***When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the company shall establish and document controls for the media.***

***Where traceability is a requirement, the company shall control and record the unique identification of the product and maintain records*** (see 4.2.4).

According to the level of traceability required by contract, regulatory, or other established requirement, the company's system shall 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; and
- d) For a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.

Note In some industry sectors, configuration management is a means by which identification and traceability are maintained (see 4.3)

*Refer to WI-71-7, Travelers*

#### **7.5.4 Customer Property**

The company shall exercise care with customer property while it is under the company's control or being used by the company. The company shall 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 shall 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**

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The company shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

Preservation of product shall 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 for sensitive products;
- d) Marking and labeling including safety warnings;
- e) Shelf life control and stock rotation; and
- f) Special handling for hazardous materials.

The company shall ensure that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.

*Refer to WI-75-3, Production Policy.*

## **7.6 Control of Monitoring and Measuring Equipment**

The company shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

***The company shall maintain a register of these monitoring and measuring equipments, 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 equipment 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.

The company shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

The company shall ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

Where necessary to ensure valid results, measuring equipment shall

- a) Be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; ***where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);***
- b) Be adjusted or re-adjusted as necessary;
- c) Have identification in order to determine its calibration status;
- d) Be safeguarded from adjustments that would invalidate the measurement result;
- e) Be protected from damage and deterioration during handling, maintenance and storage; and
- f) ***Be recalled to a defined method when requiring calibration.***

In addition, the company shall assess and ***record the validity of the previous measuring results when the equipment is found not to conform to requirements.*** The company shall take appropriate action on the equipment and any product affected. ***Records of the results of calibration and verification shall 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 shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

*Monitoring and measurement used during product realization shall be determined by documented specifications, and by technicians based upon their skill, judgment and experience.*

*Monitoring and measuring devices needed to provide evidence of conformity of product are suitably identified and recorded. Original calibration certification documents shall be maintained.*

*Monitoring and measuring devices used solely in applications which do not require high tolerance measurements do require calibration. These devices shall be considered "For Reference Only", and labeled "NOCAL".*

*Equipment must be received at the calibration facility in the same condition in which it had been used on product. Therefore, conformity of the equipment will be preserved during delivery processing, including identification, handling, packaging, storage and protection. To achieve this objective, all equipment will be delivered to the calibration facility unopened or otherwise tampered, double wrapped, boxed, and clearly identified both inside and outside the box.*

Refer to WI-76-1, Calibration

## **8.0 Measurement, Analysis and Improvement**

### **8.1 General**

The company shall plan and implement the monitoring, measurement, analysis and improvement processes needed

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

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

### **8.2 Monitoring and Measurement**

#### **8.2.1 Customer Satisfaction**

As one of the measurements of performance of the quality management system, the company shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

*Form 72-1, Customer Feedback Log shall be used to record positive and negative customer feedback. The results of the log shall be reviewed periodically and during the Management Review.*

#### **8.2.2 Internal Audit**

The company shall conduct internal audits at planned intervals to determine whether the quality management system

- a) Conforms to the planned arrangements (see 7.1), to the requirements of AS9100B/ISO 9001:2008 and to the quality management system requirements established by the company, and
- b) Is effectively implemented and maintained.

An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and

methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

***A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results. Records of the audits and their results shall be maintained (see 4.2.4).***

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

Detailed tools and techniques shall 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 shall also meet contract and/or regulatory requirements.

*Auditing activities shall focus on*

- a) *Processes,*
- b) *Intent (that the quality manual states it is going to meet all requirements of the ISO 9001:2000 standard),*
- c) *Implementation (that the requirements of the quality manual are implemented), and*
- d) *Effectiveness (that the implementation of the quality manual requirements are effective).*

*Refer to WI-82-2, Internal Audits.*

### **8.2.3 Monitoring and Measurement of Processes**

The company shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

In the event of process nonconformity, the company shall

- a) Take appropriate action to correct the nonconforming process,
- b) Evaluate whether the process nonconformity has resulted in product nonconformity, and
- c) Identify and control the any nonconforming product in accordance with (see 8.3).

### **8.2.4 Monitoring and Measurement of Product**

The company shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). ***Evidence of conformity with the acceptance criteria shall be maintained.***

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

When the company uses sampling inspection as a means of product acceptance, the plan shall be statistically valid and appropriate for use. The plan shall preclude the acceptance of lots whose samples have known nonconformities. When required, the plan shall be submitted for customer approval.

Product shall 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.

**Records shall indicate the person(s) authorizing release of product for delivery to the customer** (see 4.2.4).

The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

*Completed Travelers shall constitute the primary records substantiating conformance with acceptance criteria.*

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

- a) **Criteria for acceptance and/or rejection,**
- b) **Where in the sequence measurement and testing operations are performed,**
- c) **A record of the measurement results, and**
- d) **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 company shall ensure that records provide evidence that the product meets the defined requirements.**

**8.2.4.2 First Article Inspection: The company'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 that change invalidates the previous first article inspection result.**

*Refer to WI-72-8, First Article Inspection Report*

### **8.3. Control of Nonconforming Product**

The company shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. **A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.**

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

**The company's documented procedure shall define the responsibility for and authority for the disposition of nonconforming product and the process for approving personnel making these decisions.**

Where applicable, the company shall deal with nonconforming product by one or 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; and
- d) By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

The organization shall not use dispositions of use-as-is or repair shall only be used after approval by an authorized representative of the company responsible for design. , unless specifically authorized by the customer, if

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

The company 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.

Unless otherwise restricted in the contract, company-designed product which is controlled via a customer specification may be dispositioned by the company as use-as-is or repair, provided the nonconformity does not result in a departure from customer-specified requirements.

Product dispositioned for scrap shall 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, shall be maintained*** (see 4.2.4).

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

When nonconforming product is detected after delivery or use has started, the company shall take action appropriate to the effects, or potential effects, of the nonconformity.

In addition to any contract or regulatory authority reporting requirements, the company's system shall provide 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 company part numbers, quantity, and date(s) delivered.

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

*Refer to WI-83-1, Control of Nonconforming Product.*

#### **8.4 Analysis of Data**

The company shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

- a) Customer satisfaction (see 8.2.1),
- b) Conformity to product requirements (see 8.2.4),
- c) Characteristics and trends of processes and products including opportunities for preventive action (see 8.2.3 and 8.2.4), and

- d) Suppliers (see 7.4).

*As a minimum, data shall be gathered from F-72-1, Customer Feedback Log, F-83-2, Discrepancy Report Log, relevant vendor performance data within Quickbooks, and the Corrective and Preventive Action system. This data shall be maintained in a format suitable for management review. Other data (e.g. warranties, scraps, average lead time, and specific data required in support of objectives) shall be considered for inclusion.*

## **8.5 Improvement**

### **8.5.1 Continual Improvement**

The company shall continually improve 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**

The company shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

**A documented procedure shall be established** to define requirements for

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

*Refer to WI-84-2, Corrective and Preventive Actions.*

### **8.5.3 Preventive action:**

The company shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

**A document procedure shall be established** to define requirements for

- a) Determining potential nonconformities and their causes,
- b) Evaluating the need for action to prevent occurrence of nonconformities,
- c) Determining and implementing action needed,
- d) **Records of results of action taken** (see 4.2.4), and
- e) Reviewing the effectiveness of preventive action taken.

*Refer to WI-84-2, Corrective and Preventive Actions.*

**REFERENCE INTERNATIONAL STANDARDS:**

AS9100 Revision B      Aerospace Standard : Quality Management Systems – Aerospace - Requirements

ISO 9001:2008      Quality Management Systems - Requirements