

Plasma Ruggedized Solutions



ISO 9001:2000 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

Conformal coating, encapsulation and potting at the San Jose, CA facility, excluding design.

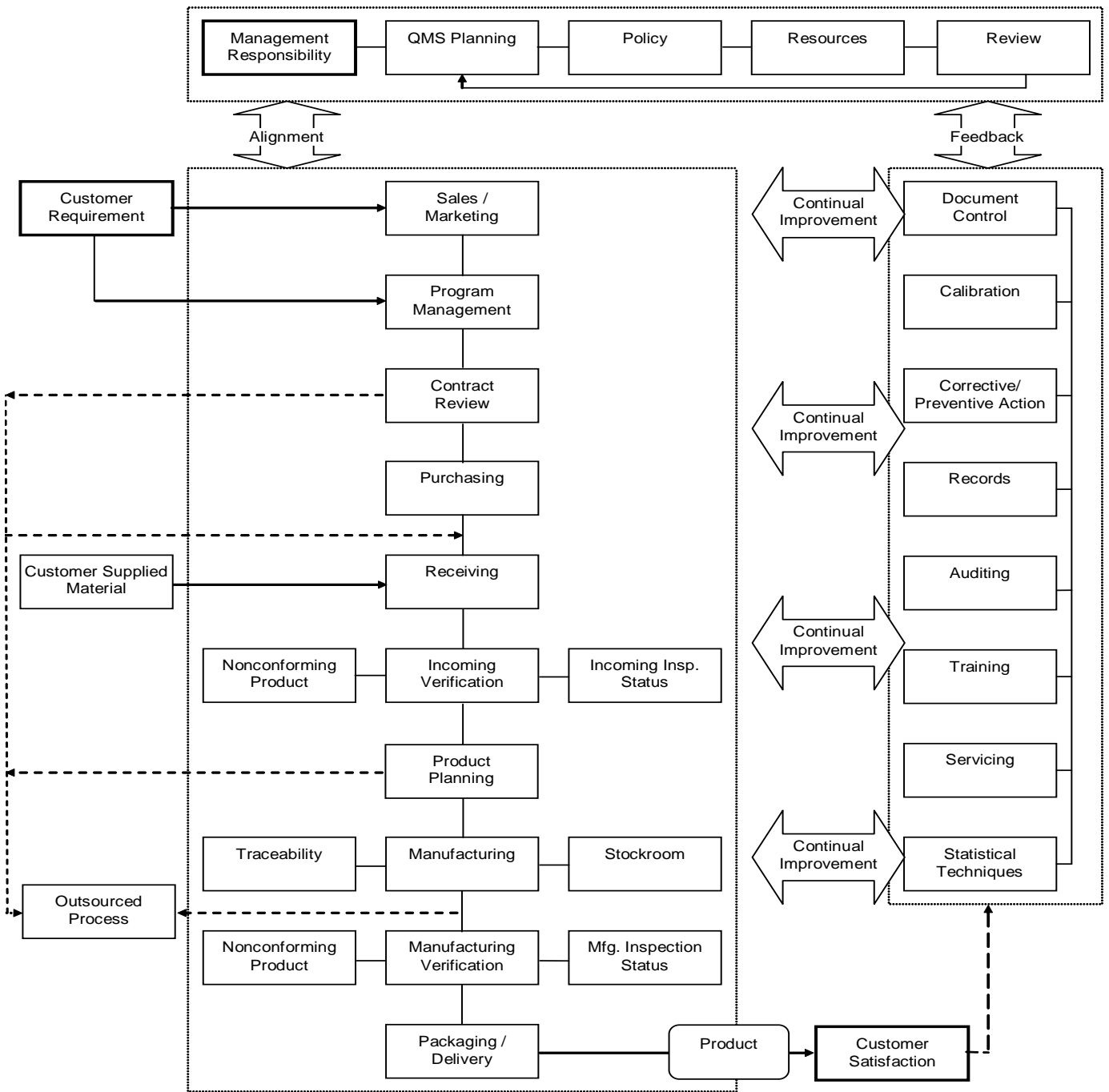
Scope Exclusions and Justifications

Clauses 7.3, Design, and 7.5.2 Special Process are excluded. PRS does not perform design. All product specifications are inspected and verified.

Note: This quality manual is written to specifically follow the ISO 9001:2000 standard 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 9001:2000 standard 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 ISO 9001:2000, and shall:

- a) Identify 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 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 ISO 9001:2000. Outsourced processes affecting conformity shall be controlled and shall be identified within the quality management system.

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 required by ISO 9001:2000,**
- d) Documents needed to ensure the effective planning, operation and control of processes, and
- e) Records required by ISO 9001:2000.

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
- 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 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.

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

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. Records shall remain legible, readily identifiable and retrievable. ***A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.***

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

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.

Quality objectives shall be posted with SPC and Pass/Fail in an 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.

5.5.1 Management Representative

Top management shall appoint a member of 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.

5.5.2 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 President, Vice President Quality Manager, and Management Representative shall participate in this review. 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 product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, Awareness and Training

The company shall

- a) Determine the necessary competence for personnel performing work affecting product quality,
- b) Provide training or take other actions to satisfy these needs,
- 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 or communication).

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.

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;
- 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.

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

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 related to the product, and

- d) Any additional requirements determined by the company.

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 Customer Contract/Purchase Order Review

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, and
- c) The company has the ability to meet the defined requirements.

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

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 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).

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, and
- c) Quality management system requirements.

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.

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.

Refer to WI-74-1, Purchasing.

7.5 Production and Service Provision

7.5.1 Control of Production and Service 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 devices,
- e) The implementation of monitoring and measure, and
- f) The implementation of release, delivery and post-delivery activities.

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 identify the product status with respect to monitoring and measurement requirements.

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

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).

7.5.5 Preservation of Product

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

7.6 Control of Monitoring and Measuring Devices

The company shall 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).

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.

Where necessary to ensure valid results, measuring equipment shall

- a) Be calibrated or verified 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;**
- 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.

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.

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 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 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 ISO 9001:2000 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. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) **shall be defined in a documented procedure**. The management responsible for the area being audited shall ensure that 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).

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, to ensure conformity of the product.

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 conformance with the acceptance criteria shall be maintained. **Records shall indicate the person(s) authorizing release of product** (see 4.2.4).

Product release and service delivery 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.

8.3. 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. **The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.**

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.

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 organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

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 7.2.1),
- c) Characteristics and trends of processes and products including opportunities for preventive action, and
- d) Suppliers.

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 cause 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), and
- f) Reviewing corrective action taken.

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 preventive action taken.

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