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MN: 4.2.2-01

PROGRESSIVE METAL  
MANUFACTURING  
COMPANY

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# QUALITY MANUAL

**Manufacturing Site - Ferndale**

1300 Channing Street  
Ferndale, MI 48220

**Warehouse**

3100 10 Mile Road  
Warren, MI 48091

Main Line: (248) 546-2827

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PRESIDENT  
Approval

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Date

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QMS Management  
Representative - Ferndale  
Approval

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Date



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## **1. SCOPE**

### **1.1 GENERAL**

The Progressive Metal Manufacturing Company (PMMCO) Management System is based on the requirements of ISO/TS 16949:2009.

The Management System is modeled after the structure and numbering of the TS Standard.

### **1.2 APPLICATION**

The only exclusions to ISO/TS 16949:2009 include Paragraph 7.3 Design and Development as it pertains to *product* design. Exclusion of this aspect of the standard does not affect the ability of PMMCO to provide product that meets customer or regulatory requirements.

## **2. NORMATIVE REFERENCE**

The following reference documents were used in the development of the PMMCO Management System:

- TS 16949:2009

## **3. TERMS AND DEFINITIONS**

## **4. QUALITY MANAGEMENT SYSTEM**

### **4.1 GENERAL REQUIREMENTS**



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PMMCO has established documented, implemented, and is maintaining a management system that is continually evaluated for effectiveness and improved upon, according to the requirements of ISO/TS 16949:2009.

PMMCO has identified the processes and their application as needed for the management system throughout the organization. Development of the processes include the:

- a. Sequence and interaction of the processes
- b. Criteria and methods required to ensure the effective operation and control
- c. Availability of resources and information needed to support process operation and monitoring
- d. Process monitoring, measuring, and analysis
- e. Implementation of actions required to meet planned results and continuous process improvement

Processes are managed by PMMCO according to the requirements of ISO/TS 16949:2009. PMMCO exercises control over outsourced processes that affect product conformity to requirements.

Reference: Process Matrix (MN: 4.2.2-01-10)  
Application, Sequence, and Interaction Chart (MN: 4.2.2-01-12)  
Process Turtles (MN: 4.2.2-01-01 through MN: 4.2.2-01-08)

#### 4.1.1 GENERAL REQUIREMENTS – SUPPLEMENTAL

Control over outsourced processes does not absolve PMMCO of responsibility for all customer requirements.

## 4.2 DOCUMENTATION REQUIREMENTS

### 4.2.1 GENERAL



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The PMMCO Management System includes the following documentation:

- a. Quality policy that is supported by measurable objectives
- b. This Management System Manual
- c. Documented procedures required by the ISO/TS 16949:2009 Standards.
- d. Additional documentation needed by PMMCO to ensure effective planning, operation and control of processes to include the records required by the above mentioned international standards.

#### 4.2.2 MANAGEMENT SYSTEM MANUAL

This Management System Manual includes:

- a. A defined scope and justification for exclusions as stated in Section 1.2
- b. References to all management system procedures
- c. A description of the interaction between processes within the Management system.

Reference: Plan, Do, Check, Act (PDCA) Diagram (Appendix – A).

#### 4.2.3 CONTROL OF DOCUMENTS

A controlled document is any document, hardcopy or electronic media required by the PMMCO Management System. Documentation comprises the following types of documents at a minimum:

- This Management System Manual
- Standard Operating Procedures (SOPs)
- Control Plans
- Standard Work Instruction (SWIs)
- Standard Operating Forms (SOFs)



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- Records
- Product Technical Specifications and Drawings
- Automotive Reference Manuals
- Standards and Codes

PMMCO maintains a procedure to identify the responsibilities and methods for the creation and modification of the various types of documents within the Management System.

Reference: SOP: 4.2.3-01, Documentation Requirements

PMMCO has implemented a procedure for controlling all documents required by ISO/TS 16949:2009 that defines the controls and responsibilities to:

- a. Approve documents for adequacy prior to use
- b. Periodically review and update as necessary and re-approve documents
- c. Ensure that changes and the current revision status of documents are identified.
- d. Ensure that relevant versions of applicable documents are available at locations. Ensure that documents remain legible and readily identifiable
- e. Ensure that documents of external origin are identified and that their distribution is controlled
- f. Prevent the unintended use of obsolete documents and apply suitable identification when retained for legal/ knowledge preservation purposes.

The Management System document Master List is maintained by the Quality System Manager.



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#### 4.2.3.1 Engineering Specifications

The PMMCO Engineering Department reviews, distributes, and implements all Customer Engineering Specifications and changes in a timely manner. Procedure requirements facilitate the updating of all appropriate documentation, and the establishment of the effective dates of the subsequent changes.

Changes to documents and data are reviewed and approved. The reviewing authority has access to pertinent background information as necessary to base this review and approval. Where practical, the nature of the change is identified in the document.

A Master List identifying the current revision status of customer-supplied drawings and customer engineering specifications, where applicable, is maintained by Engineering.

Reference: SOP: 4.2.3-02, Engineering Specifications

#### 4.2.4 CONTROL OF RECORDS

Management System records are maintained to demonstrate conformance to specifications and the effectiveness of the Management System.

Quality records are legible and stored in a manner that provides for retrieval and protects against loss/damage.

PMMCO identifies responsibilities for the identification, collection, indexing, filing, protection, storage, and disposition of quality records.

Specific retention times including responsibility and location of records are found at the end of each procedure. The following records are retained for the length (minimum) stated:



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- Production part approvals, tooling records and customer purchase orders/ amendments for the length of time that the part (or family of parts) is active for production plus service parts plus one calendar year unless otherwise specified by the customer.
- Quality performance records are maintained for one calendar year after they were initiated.
- Internal audits of the Management System and records of review are maintained for three years.
- All records are subject to customer extended requirements.

Quality records received from suppliers are an element of PMMCO quality records.

Reference: SOP: 4.2.4-01, Record Retention

#### 4.2.4.1 Records Retention

The controls applied to records satisfy regulatory and customer requirements.

## **5. MANAGEMENT RESPONSIBILITY**

### **5.1 MANAGEMENT COMMITMENT**

Top Management is depicted in the PMMCO Organizational Chart. Top Management is committed to improving the effectiveness of the Management System by:

- a. Communicating the importance of Customer requirements and all state/federal regulations to PMMCO, as applicable
- b. Establishing Quality Policies supported by measurable objectives
- c. Ensuring that employees have all the necessary resources to meet the objectives



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d. Conducting Management Reviews

**5.1.1 PROCESS EFFICIENCY**

Product realization processes and the supporting processes are reviewed in Management Review Meetings in order to assure effectiveness and efficiency of the processes.

**5.2 CUSTOMER FOCUS**

Top Management ensures that customer requirements are identified during the Product Realization Planning process with the goal of enhancing customer satisfaction.

The Management Team as represented by the Quality Management Representative will notify the Registrar in the following situations:

- GM New Business Hold
  - Registrar must be notified within 5 days, refer to GM 1746 for details
- GM Controlled Shipping Level II (Level II Containment)
  - Registrar must be notified within 5 days
- DaimlerChrysler Needs Improvement
  - Registrar must be notified within 5 days
- Ford Q1 Revocation
  - Registrar must be notified within 5 days

Reference: SOP: 7.1-01, Product Realization Planning

**5.3 QUALITY POLICIES**

The PMMCO Quality Policies are developed and approved by Top Management. PMMCO management is responsible to ensure the Quality Policies:



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- a. Are appropriate to the nature, scale, of the activities present.
- b. Include a commitment to comply with all requirements, and to continually improve the effectiveness of the Management System.
- c. Provides the basis for development and review of Quality objectives.
- d. Communicated and understood at all levels of the organization.
- e. Are explained and discussed during employee orientation training and posted in conspicuous locations throughout the company.

Policies are reviewed for their continuing suitability during Management Review.

Reference: SOP: 5.6-01 Management Review (SOF: 5.6-01-01 Quality Policy)

## **5.4 PLANNING**

### **5.4.1 MANAGEMENT SYSTEM OBJECTIVES**

- Top Management ensures that objectives are established at relevant functions and levels at PMMCO. Management System objectives are developed to be measurable and consistent with the Policies. Progress towards achieving the objectives is reported to employees at Shop-wide Meetings. Copies of the Shop wide presentations are posted throughout the plant.

#### **5.4.1.1 Quality Objectives – Supplemental**

Top Management has defined, within the business plan, the Objectives used to deploy the Management System Policies.

### **5.4.2 MANAGEMENT SYSTEM PLANNING**

Planning of the Management System by Top Management is conducted to:



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- a. Meet the requirements identified in Paragraph 4.1
- b. Achieve the goals of the Quality objectives
- c. Ensure the integrity of the system is maintained when changes are planned and implemented

## **5.5 RESPONSIBILITY, AUTHORITY, AND COMMUNICATION**

### **5.5.1 RESPONSIBILITY AND AUTHORITY**

PMMCO Top Management is ultimately responsible for establishing, implementing, and maintaining the Management System. See the PMMCO Organizational Chart.

The following documents within the Management System define responsibility and authority:

- Organizational Chart
- Job Descriptions
- This Management System Manual
- Procedures and work instructions

Reference: PMMCO Organizational Chart (MN: 4.2.2-01-11)

#### **5.5.1.1 Responsibility for Quality**

Managers and other employees with responsibility and authority for corrective actions are promptly informed of product or processes which do not conform to requirements. PMMCO personnel responsible for product quality have the authority to stop production and correct problems. Manufacturing operations on all shifts are staffed with personnel who are in charge of and delegated responsibility for ensuring quality product.

Reference: SOP: 8.3-01, Control of Nonconforming Product



## 5.5.2 MANAGEMENT REPRESENTATIVE

The President has appointed the Quality Systems Manager as the Management Representative for ISO/TS 16949:2009. The Management Representatives are responsible for:

- a. Ensuring that processes needed for the Management System are established, implemented, and maintained in accordance with the appropriate standards
- b. Reporting to Top Management on the performance of the system and any need for improvement
- c. Promoting the awareness of customer and environmental requirements during shop-wide and departmental meetings

### 5.5.2.1 Customer Representative

The President has appointed the Quality Manager as the Customer Representative. The Customer Representative appoints personnel with responsibility and authority to ensure customer requirements, such as the following, are addressed:

- Special Characteristics
- Setting quality objectives and related training
- Corrective and preventive actions
- Process design and development

## 5.5.3 INTERNAL COMMUNICATION

Top Management communicates the effectiveness of the Management System throughout the organization with the following:

- Plant Meetings



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- Departmental Meetings
- Plant Bulletin Boards
- Posted graphs and charts

## **5.6 MANAGEMENT REVIEW**

### **5.6.1 GENERAL**

The Management System effectiveness is reviewed at least twice per year by Top Management and documented. The purpose of the review is to assess the adequacy, effectiveness and continuing suitability of the Management System. The Management review includes evaluating opportunities for improvement and necessary changes to the Management System including:

- Policies and Objectives

Records of the Management Review are maintained.

Reference: SOP: 5.6-01, Management Review

#### **5.6.1.1 Quality Management System Performance**

Management Reviews include all requirements of the Management System and its performance trends. This review is an essential part of the continual improvement process. Monitoring of Management System Objectives and the cost of poor quality is part of this review. Evidence of achievement of the Objectives and of customer satisfaction is recorded.

### **5.6.2 REVIEW INPUT**

Top Management conducts Management Review meetings that address the following inputs at a minimum:



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- a. Results of audits including internal, external, and customer
- b. Customer feedback
- c. Process performance and conformity
- d. Status of Preventive and Corrective Action
- e. Progress made on action items identified at the previous meeting
- f. Changes that could affect the Management System
- g. Recommendations for Continuous Improvement

Reference: SOP: 5.6-01, Management Review

### **5.6.2.1 Review Input – Supplemental**

Input includes actual and potential field-failures and their impact on quality, safety, and environment.

### **5.6.3 REVIEW OUTPUT**

The output of PMMCO Management Review includes at a minimum:

- a. Improvement of the effectiveness of the Management System and its processes
- b. Improvement of product related to customer requirements
- c. Adjusted resource allocation

Reference: SOP: 8.5.1-01, Continual Improvement

## **6. RESOURCE MANAGEMENT**

### **6.1 PROVISION OF RESOURCES**

PMMCO has determined and provided the resources needed to:



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- Implement, maintain, and continually improve Management System effectiveness; and
- Enhance customer satisfaction by meeting customer requirements.

This has been accomplished through:

- Use of the Product Realization Planning process;
- Monitoring and measuring both manufacturing and **environmental** processes; and
- Reviewing output data during the Management Review process.

## 6.2 HUMAN RESOURCES

### 6.2.1 GENERAL

PMMCO personnel performing work or affecting product quality are competent based on evaluation of their education, training, skills, and experience. Competence levels are defined and documented on individual Job Descriptions.

### 6.2.2 COMPETENCE, AWARENESS, AND TRAINING

PMMCO identifies the education, skills, experience and training needs for all personnel and provides training for:

- a. Meeting job requirements
- b. Quality Policies and Objectives

PMMCO evaluates the effectiveness of training provided when it affects the quality of product.



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PMMCO ensures that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of Quality Objectives.

Records of education, training, skills and experience are maintained.

Reference: SOP: 6.2.2-01, New Employee Orientation  
SOP: 6.2.2-02, Human Resources/ Departmental Training  
SOP: 6.2.2-03, Employee Motivation/ Empowerment

### **6.2.2.1 Product Design Skills**

PMMCO is not responsible for product design at this time.

### **6.2.2.2 Training**

Documented procedures describe how training needs are identified and how competency of all personnel is achieved. All personnel performing specific tasks are qualified with particular attention paid to customer satisfaction.

### **6.2.2.3 Training on the Job**

Personnel receive on-the-job training for new or modified jobs. This training includes informing the personnel of the consequences to the customer of nonconformities.

### **6.2.2.4 Employee Motivation and Empowerment**

PMMCO maintains a process to motivate employees to achieve quality objectives, to make continuous improvement suggestions and to create an environment that promotes innovation. This process promotes quality and technological awareness throughout the organization by the following:

- Bonus Plan contributions related to quality performance
- Suggestion program with awards



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- Tuition reimbursement plan

### **6.3 INFRASTRUCTURE**

PMMCO has identified, provided and maintains the infrastructure required to achieve conformity to product requirements. Infrastructure includes:

- a. Buildings, workspace and associated utilities;
- b. Process equipment (both hardware and software); and
- c. Supporting services.

Reference: SOP: 6.3-01, Infrastructure Maintenance

#### **6.3.1 PLANT, FACILITY, AND EQUIPMENT PLANNING**

PMMCO facilities, equipment and processes are developed using a multi-disciplinary approach.

Reference: SOP: 6.3-01, Infrastructure Maintenance

The PMMCO plant layout is based on synchronous material flow while optimizing material travel, handling and value-added use of floor space. Effectiveness of existing operations is monitored and evaluated during Management Review.

#### **6.3.2 CONTINGENCY PLANS**

PMMCO has established contingency plans to satisfy customer requirements in the event of an emergency.

Reference: SOP: 6.3-02, Contingency Plans

### **6.4 WORK ENVIRONMENT**



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PMMCO manages the work environment to achieve conformity to product requirements during the Advanced Product Realization Planning process.

Reference: SOP: 7.1-01, Product Realization Planning

#### 6.4.1 PERSONNEL SAFETY TO ACHIEVE PRODUCT QUALITY

PMMCO addresses product safety and methods to minimize potential risks to the production operator in manufacturing process activities.

Reference: SOP: 6.4-01, Compliance with Safety and Environmental Regulations

#### 6.4.2 CLEANLINESS OF THE PREMISES

PMMCO maintains the premises in a state of order, cleanliness and repair that is consistent with our product and manufacturing.

Reference: SOP: 6.4.2-01, Safety and Cleanliness of Premises

### **7. PRODUCT REALIZATION**

#### **7.1 PLANNING OF PRODUCT REALIZATION**

PMMCO designs and develops the manufacturing process for each part number manufactured during Product Realization Planning.

Product Realization Planning is consistent with other requirements of the Management System.

Planning of product realization results in determining the following:

- a. Quality objectives and requirements of the product
- b. The need to establish processes, documents, and provide resources specific to the product



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- 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 meets customer requirements

The output of the planning process is typically the items included in a Production Part Approval Process (PPAP) submission.

Reference: SOP: 7.1-01, Product Realization Planning

Reference: SOP: 7.1-03, Advance Product Quality Planning – Pre-Launch

Reference: SOP: 7.1-04, Final Product Audit (CS-1)

#### 7.1.1 PLANNING OF PRODUCT REALIZATION – SUPPLEMENTAL

Customer requirements and references to technical specifications are included in the Quality Plan.

#### 7.1.2 ACCEPTANCE CRITERIA

Acceptance criteria for product are defined by PMMCO during Product Realization Planning process. This criteria is approved by the customer, where required. The acceptance level for attribute data sampling is zero defects.

#### 7.1.3 CONFIDENTIALITY

PMMCO ensures the confidentiality of customer-contracted products/ projects under development and the associated information.



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#### 7.1.4 CHANGE CONTROL

PMMCO has documented procedures to control and react to changes that impact product realization. The effects of any change, including suppliers, are assessed, verified and validated to ensure compliance with customer requirements. **When required by the customer, PMMCO obtains customer approval or wavier prior to production implementation.** Changes are validated prior to implementation.

Reference: SOP: 7.1-03, Advance Product Quality Planning – Pre-Launch

### 7.2 CUSTOMER-RELATED PROCESSES

#### 7.2.1 DETERMINATION OF REQUIREMENTS RELATED TO THE PRODUCT

PMMCO maintains documented procedures to determine the following:

- a. Customer specified requirements including delivery and post delivery activities
- b. Requirements not stated by the customer but necessary for specified or intended use
- c. Compliance to all applicable government, safety regulations as applied to acquisition, storage, handling, recycling, elimination or disposal of materials
- d. Additional requirements determined by PMMCO

Reference: SOP: 7.2.1-01, Quote Procedure

Reference: SOP: 7.2.1-02, Determination and Implementation of Customer-Specific Requirements

Reference: SOP: 7.1-01, Product Realization Planning



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### 7.2.1.1 Customer Designated Special Characteristics

PMMCO maintains documented procedures to identify responsibilities for identification, data collection, analysis and maintenance of records for customer special characteristics. **When required by the customer, PMMCO uses customer designated systems for key characteristics.**

Reference: SOP: 7.1-01, Product Realization Planning

Reference: SOP: 8.1-01, Statistical Techniques

### 7.2.2 REVIEW OF ENVIRONMENTAL AND PRODUCT REQUIREMENTS

PMMCO reviews all product requirements prior to our commitment to supply the product to the customer. This review includes changes to the contract or order.

This review verifies:

- a. The requirements are adequately defined and documented.
- b. Any requirements differing from the previous quote are resolved.
- c. Ability to meet contract requirements.

Records of Contracts and Contract amendment reviews are maintained.

PMMCO confirms customer requirements not stated prior to acceptance.

Reference: SOP: 7.2.2-01, Contract Review

PMMCO ensures that when product requirements are changed, that relevant documents are amended and relevant personnel are made aware of changed product requirements.

Reference: SOP: 7.2.2-01, Contract Review



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### **7.2.2.1 Review of Requirements Related to the Product – Supplemental**

Waiving the requirement for a formal review requires customer authorization.

### **7.2.2.2 Organization Manufacturing Feasibility**

PMMCO conducts a multi-disciplinary team feasibility study to confirm and document the manufacturing feasibility of the proposed products including risk analysis.

Reference: SOP: 7.1-01, Product Realization Planning

### **7.2.3 CUSTOMER AND EXTERNAL COMMUNICATION**

PMMCO has implemented procedures to ensure and maintain effective communications with the customer regarding:

- a. Product information
- b. Enquiries, contracts or order handling including contract amendments
- c. Customer feedback to include customer complaints

Reference: SOP: 8.2.1-01, Measurement of Customer Satisfaction

Reference: SOP: 5.5.3-01, Internal/ External Communication

### **7.2.3.1 Customer Communication – Supplemental**

PMMCO has the ability to communicate necessary information, including data, in a customer specified language or electronic format.

Reference: SOP: 7.2.3-01, Shipment Scheduling and Notification



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### **7.3 DESIGN AND DEVELOPMENT**

The following design requirements apply only to the design of processes. PMMCO does not design product.

#### **7.3.1 Design and Development Planning**

PMMCO establishes design plans, which include the following:

- The design and development stages
- The review, verification, and validations appropriate to each stage
- The responsibilities and authorities for the design and development

The interfaces between different groups involved in the design and development project are managed to ensure effective communication and clear assignment of responsibility. Plans are updated as the design and development project progresses.

##### **7.3.1.1 Multidisciplinary Approach**

A multidisciplinary approach is used for development/ finalization of special characteristics, development and review of FMEAs with actions to reduce risks, and development and review of control plans.

#### **7.3.2 Design and Development Inputs**

Inputs to design and development are determined and recorded for the following categories:

- Functional and performance requirements
- Applicable statutory and regulatory requirements
- Information from previous designs
- Other essential requirements



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Inputs are reviewed for adequacy. This review ensures that requirements are complete, unambiguous and not in conflict with each other.

### **7.3.2.1 Product Design Input**

PMMCO does not design product.

### **7.3.2.2 Manufacturing Process Design Input**

PMMCO identifies documents and reviews the following inputs for process design:

- Product design output data
- Targets for productivity, process capability and cost
- Customer requirements
- Experience from previous developments

### **7.3.2.3 Special Characteristics**

PMMCO has identified all special characteristics in the Control Plan and all process control documents for each part number. PMMCO complies with customer-specified definitions and symbols.

Reference: SOP: 7.1-01, Product Realization Planning

Reference: SOP: 8.1-01, Statistical Techniques

## **7.3.3 DESIGN AND DEVELOPMENT OUTPUTS**

Outputs are provided in a form that allows for verification against input. Output is approved prior to release.

Design and development outputs:

- Meet input requirements



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- Provide appropriate information for purchasing, product and service provision
- Contain or reference process acceptance criteria
- Specify the essential characteristics for safe and proper use of the process

### **7.3.3.1 Product Design Outputs – Supplemental**

PMMCO does not design products.

### **7.3.3.2 Manufacturing Process Design Output**

Manufacturing design outputs are expressed in terms that can be verified and validated against manufacturing process design input requirements.

Manufacturing process design outputs include:

- a. Specifications and drawings
- b. A manufacturing process flow
- c. Manufacturing process FMEA
- d. Control Plan
- e. Work Instructions
- f. Process approval acceptance criteria
- g. Data for quality, reliability, maintainability and measurability
- h. Results of error proofing activities as appropriate
- i. Methods of rapid detection and feedback of product/ manufacturing process nonconformance's

Reference: SOP: 7.1-01, Product Realization Planning

Reference: SOP: 7.1-03, Advance Product Quality Planning – Pre-Launch

### **7.3.4 DESIGN AND DEVELOPMENT REVIEW**



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Systematic reviews are held at suitable stages according to the Design and Development Plan. The reviews ensure the ability of design and development results to meet requirements, identify problems, and propose necessary actions.

Reviews include representatives of the functions concerned. Results of the reviews and necessary actions are maintained.

#### **7.3.4.1 Monitoring**

Measurements of design and development are taken, analyzed, and reported at appropriate stages as defined in the Design and Development Plan. Summarized results of these measurements are input for Management Review.

#### **7.3.5 DESIGN AND DEVELOPMENT VERIFICATION**

Verification is performed according to the Design and Development Plan. This verification ensures that the design and development outputs meet the input requirements. Records of verification and any resulting actions are maintained.

#### **7.3.6 DESIGN AND DEVELOPMENT VALIDATION**

Validation is performed according to the Design and Development Plan. Validation ensures the ability of process is capable of meeting the intended application or use. Validation is completed prior to the delivery or implementation of product. Records of validation and any resulting actions are maintained.

##### **7.3.6.1 Design and Development Validation – Supplemental**

Validation is performed according to customer requirements and program timing.

##### **7.3.6.2 Prototype Program**



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When required by the customer, PMMCO develops a Prototype Control Plan. PMMCO will use the same suppliers, tooling and manufacturing process that will be used in production whenever possible.

All inspection activities are monitored for timely completion and conformance to requirements.

When outsourcing is part of the process, PMMCO provides all the necessary assistance to the supplier to include technical assistance.

Reference: SOP: 7.1-01, Product Realization Planning

### **7.3.6.3 Product Approval Process**

PMMCO follows customer designated product and manufacturing approval processes (e.g. **AIAG PPAP manual**). Product approval is the last step after validation of the manufacturing process.

Reference: SOP: 7.3.6-01, Production Part Approval Process

### **7.3.7 CONTROL OF DESIGN AND DEVELOPMENT CHANGES**

Design and Development changes are identified and recorded. Changes are reviewed, verified, validated, and approved prior to implementation. **When required by the customer, PMMCO obtains customer approval or wavier prior to production implementation.** Reviews include the evaluation of the effect changes have on constituent parts and product already delivered.



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## **7.4 PURCHASING**

### **7.4.1 PURCHASING PROCESS**

PMMCO has implemented procedures to ensure that purchased product and services conforms to specified purchase requirements.

The type and extent of control applied to the supplier and purchased product or service is dependant upon the effect of the product or service on the subsequent product realization or the final product.

PMMCO has implemented a procedure to evaluate and select suppliers based on their ability to supply product or services in accordance with PMMCO requirements. The procedures identify criteria for selection, evaluation and re-evaluation.

PMMCO evaluates changes within the supplier's organizational structure to ensure the continuity of the Supplier's Quality Management System. Records of the evaluations and necessary actions arising from the evaluation are maintained

Reference: SOP: 7.4.1-01, Purchasing & Supplier Qualification

Reference: MN: 4.2.2-02, Supplier Quality Manual

#### **7.4.1.1 Regulatory Conformity**

All products purchased by PMMCO are required to conform to applicable regulatory requirements.

#### **7.4.1.2 Supplier Quality Management System Development**

The goal of the PMMCO supplier program is conformance to ISO/TS 16949. Registration to ISO 9001 is required unless otherwise specified by the customer.

Other requirements are located in the Supplier Quality Manual (MN: 4.2.2-02).



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Reference: SOP: 8.5.2-02, Supplier Corrective Action

Reference: MN: 4.2.2-02, Supplier Quality Manual

### **7.4.1.3 Customer-approved Sources**

PMMCO purchases product, material or services from approved sources when specified by the contract. This does not relieve PMMCO of responsibility to ensure the quality of purchased product or service.

### **7.4.2 PURCHASING INFORMATION**

PMMCO purchase orders for product or services contain the following information as applicable:

- a. Requirements for approval of product, procedures/ processes and equipment
- b. Requirements for qualifications of personnel
- c. Quality Management System requirements

PMMCO reviews and approves purchase orders prior to the communication to the Supplier.

Reference: SOP: 7.4.1-01, Purchasing & Supplier Qualification

### **7.4.3 VERIFICATION OF PURCHASED PRODUCT**

PMMCO has implemented a Receiving Inspection procedure to ensure that purchased product or service that affects the quality of the product meets the specified purchase requirements.

Reference: SOP: 7.4.3-01, Receiving Purchased Materials and Purchased Components



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When PMMCO or our Customer intends to perform verification at the Supplier's facility, the verification arrangement and method of release is stated on the purchase order.

#### **7.4.3.1 Incoming Product Quality**

PMMCO has implemented a Receiving Inspection procedure to ensure that purchased product or service that affects the quality of the product using one or more of the following methods:

- a. Receipt and evaluation of statistical data by the Supplier
- b. Receiving Inspection sampling plan based on performance
- c. Second or third party audits of Supplier sites, when combined with records of acceptable delivered product
- d. Part evaluation by a designated laboratory
- e. Other methods agreed upon by the Customer

Reference: SOP: 7.4.3-01, Receiving Purchased Materials and Purchased Components

#### **7.4.3.2 Supplier Monitoring**

PMMCO Supplier performance is monitored using the following indicators:

- a. Delivered product quality
- b. Customer complaints including returned product and field failures
- c. Delivery performance including instances of premium freight
- d. Special status customer notifications related to quality or delivery issues

**NOTE:** This paragraph applies to Suppliers of product or services that become part of the end product. They are identified by PMMCO as "Direct Suppliers."



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PMMCO promotes Supplier monitoring of their manufacturing process performance.

Reference: SOP: 7.4.1-01, Purchasing & Supplier Qualification

## **7.5 PRODUCTION AND SERVICE PROVISION**

### **7.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION**

PMMCO carries out production under the following controlled conditions as applicable:

- a. Availability of information describing the product characteristics
- b. Availability of necessary work instructions
- c. Use of suitable equipment
- d. Availability and use of monitoring and measuring devices
- e. Implementation of monitoring and measuring
- f. Implementation of release and delivery activities.

Reference: SOP: 7.5.1-01, General Job-Run

#### **7.5.1.1 Control Plan**

PMMCO develops a Control Plan for each part number. Control Plans that take into account the Design FMEA, when provided by the customer, and Manufacturing FMEA outputs are identified as either Pre-Launch or Production. PMMCO Control Plans include:

- a. The controls used for the manufacturing process
- b. Methods for monitoring of control exercised over special characteristics defined by either PMMCO or the Customer
- c. Customer required information as applicable



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- d. The specified reaction plan when the process becomes unstable or not statistically capable

Control Plans are reviewed and updated when any change occur, affecting product, manufacturing process, measurement, logistics, supply sources or FMEA.

Customer requirements for approval of revised Control Plans are evaluated according to the requirements of the PPAP manual.

Reference: SOP: 7.1-01, Production Realization Planning

#### **7.5.1.2 Work Instructions**

PMMCO maintains documented Work Instructions for all employees having the responsibilities for the operation of processes that impact product quality. Work Instructions are available at the work stations.

#### **7.5.1.3 Verification of Job Set-ups**

Manufacturing job set-ups are verified at the start of each run and at running production lot changes.

Set-up personnel are provided with work instructions to complete the set-up.

Reference: SOP: 7.5.1-01, General Job-Run

#### **7.5.1.4 Preventive and Predictive Maintenance**

PMMCO has identified key process equipment and provides resources for machine/ equipment maintenance. The PMMCO Preventive Maintenance Plan includes the following:

- a. Planned maintenance activities
- b. Packaging and preservation of equipment, tooling and gauging



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- c. Inventory of replacement parts for key manufacturing equipment
- d. Reporting, evaluating and improving maintenance objectives

PMMCO uses an electronic database to enhance predictive maintenance methods for continuous improvement in effectiveness and efficiency of production equipment.

Reference: SOP: 6.3-01, Infrastructure Maintenance

#### **7.5.1.5 Management of Production Tooling**

PMMCO provides resources for tool and gauge design, fabrication and verification.

PMMCO maintains a procedure for production tooling management that includes:

- a. Maintenance and repair facilities and personnel
- b. Storage, recovery and set-up
- c. Tool change programs for perishable tooling
- d. Tool design modification documentation with engineering change level
- e. Tool modification and revision to documentation
- f. Tool identification, defining status i.e.; production, repair or disposal

PMMCO verifies any outsourced tool work.

Reference: SOP: 7.5.1-02, Tooling Management

Reference: SOP: 7.5.1-03, Outsource Tooling Review



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### **7.5.1.6 Production Scheduling**

PMMCO has a documented procedure to plan production processes to meet customer delivery requirements. The computer database provides production information at key stages in the process. All production processes are order driven.

Reference: SOP: 7.5.1-01, General Job-Run

Reference: [CMS Data Base- Work Order](#)

### **7.5.1.7 Feedback of Information from Service**

PMMCO maintains a process for communicating service concerns to manufacturing and engineering activities.

### **7.5.1.8 Service Agreement with Customer**

PMMCO does not enter into service agreements at this time.

## **7.5.2 VALIDATION OF PROCESSES FOR PRODUCTION AND SERVICE PROVISION**

PMMCO validates its production processes in order to demonstrate ability to achieve planned results. Arrangements for these processes include the following as applicable:

- Defined review and approval criteria
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures
- Requirements for records
- Revalidation

Reference: SOP: 7.1-01, Product Realization Planning



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Reference: SOP: 7.1-03, Advance Product Quality Planning – Pre-Launch

Reference: SOP: 7.3.6-01, Production Part Approval Process

### **7.5.2.1 Validation of Processes for Production and Service Provision – Supplemental**

PMMCO performs validation for all production processes.

### **7.5.3 IDENTIFICATION AND TRACEABILITY**

PMMCO maintains a procedure for the identification and product status, with respect to monitoring and measurement requirements, throughout product realization.

Where traceability is a requirement, unique identification of the product is recorded.

Reference: SOP: 7.5.3-01, Product ID & Traceability

### **7.5.3.1 Identification and Traceability – Supplemental**

Product is always suitably identified at PMMCO.

### **7.5.4 CUSTOMER PROPERTY**

PMMCO has procedures to maintain customer owned property while being used.

Procedures provide for:

- Identification
- Verification
- Protection of customer property intended for use or incorporation into the product
- Reporting of lost, damaged or otherwise unsuitable for use



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Records are maintained.

Reference: SOP: 7.5.4-01, Customer Property

#### **7.5.4.1 Customer-owned Production Tooling**

PMMCO permanently marks customer owned tools (manufacturing, test, inspection tooling and equipment) so that ownership is visible.

Reference: SOP: 7.5.1-02, Tooling Management

#### **7.5.5 PRESERVATION OF PRODUCT**

PMMCO procedures ensure that the conformity of product is preserved during internal processing and delivery to the customer. Preservation includes identification, handling, packaging, storage and protection. Preservation also extends to assembly components.

Reference: SOP: 7.5.5-01, Preservation of Product

#### **7.5.5.1 Storage and Inventory**

PMMCO inspects the condition of stored product at planned intervals.

PMMCO uses a First in First Out inventory management system to ensure stock rotation. Obsolete product is considered nonconforming product and quarantined until disposition is resolved.

Reference: SOP: 7.5.5-01, Preservation of Product

### **7.6 CONTROL OF MONITORING AND MEASURING DEVICES**



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PMMCO determines the method of monitoring and measuring and the devices required to provide evidence of product conformity during the Product Realization Planning process.

Reference: SOP: 7.1-01, Product Realization Planning

Monitoring/ measurement equipment and the frequency of use are identified for each sequence of a manufacturing process on the Inspection Report.

Reference: SOP: 8.2.4-01, Inspection and Testing

Measuring equipment used at PMMCO ensures valid results through:

- a. Calibration, verification at specified intervals or prior to use, against measurement standards traceable to international or national standards. When standards do not exist, the basis used for calibration or verification is recorded.
- b. Adjusting or re-adjusting as needed
- c. Identification to enable the calibration status to be known
- d. Safeguarding from adjustments that would invalidate the measurement result
- e. Protecting from damage and deterioration during handling, maintenance and storage.

If equipment is found to be out of calibration, validity of prior inspections is assessed and customers are notified if shipment of suspect product is involved. Records of calibration and verification are maintained.

Reference: SOP: 7.6-01, Control of Monitoring and Measuring Devices

Computer software used in the monitoring and measuring of specified requirements is confirmed prior to initial use and reconfirmed as necessary.



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### 7.6.1 MEASUREMENT SYSTEM ANALYSIS

PMMCO uses statistical studies to determine the variation present in the results of each type of measuring and test equipment identified on the Control Plan as requiring SPC.

The analytical methods and acceptance criteria used conforms to the MSA manual. Other analytical methods and acceptance criteria must be approved by the customer.

### 7.6.2 CALIBRATION/ VERIFICATION RECORDS

Records include:

- a. Equipment identification and measurement standard used
- b. Revisions following engineering changes
- c. Any out-of-specification readings when received
- d. An assessment of the impact of the out-of-specification condition
- e. Statements of conformity to the specification after calibration
- f. Notification to the customer of suspect conditions

### 7.6.3 LABORATORY REQUIREMENTS

#### 7.6.3.1 Internal Laboratory

PMMCO internal laboratories have defined scopes to include capability to perform required inspections, tests and calibration services. Laboratory scopes are defined in applicable procedures to specify and implement requirements for:

- a. Adequacy of laboratory procedures
- b. Competency of laboratory personnel
- c. Testing of product



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- d. Capability to perform these services correctly, traceable to relevant ASTM standards
- e. Review of related records.

Reference: SOP: 7.6.3-01, Quality Laboratory

### **7.6.3.2 External Laboratory**

External laboratories used by PMMCO for inspection, test or calibration services have defined laboratory scopes including the capability to perform the required inspection, test or calibration as evidenced by ISO/IEC 17025 certification.

Calibration services are performed by the equipment manufacturer when a qualified laboratory is not available for a specific piece of equipment. The requirements of 7.6.3.1 are applicable to the equipment manufacturer.

## **8. MEASUREMENT, ANALYSIS, AND IMPROVEMENT**

### **8.1 GENERAL**

PMMCO procedures address the planning and implementation of monitoring, measurement, analysis and improvement processes needed to:

- a. Demonstrate conformity of product
- b. Ensure conformity of the Management System
- c. Continually improve the effectiveness of the Management System.

Procedures address applicable methods, including statistical techniques, and the extent of their use. See referenced procedures in sub paragraphs.

#### **8.1.1 IDENTIFICATION OF STATISTICAL TOOLS**



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PMMCO determines the use of statistical techniques in each manufacturing process during the Product Realization Planning process.

Reference: SOP: 8.1-01, Statistical Techniques

### 8.1.2 KNOWLEDGE OF BASIC STATISTICAL CONCEPTS

PMMCO provides employees with training in basic statistical concepts such as variation, control, process capability and over adjustment. Records of training are maintained.

## 8.2 MONITORING AND MEASUREMENT

### 8.2.1 CUSTOMER SATISFACTION

PMMCO maintains a procedure to monitor the customer's perception of the level which PMMCO has met customer requirements.

Reference: SOP: 8.2.1-01, Measurement of Customer Satisfaction

#### 8.2.1.1 Customer Satisfaction – Supplemental

PMMCO monitors customer satisfaction through continual evaluation of performance of the product realization processes. Performance indicators are based on objective data including at a minimum:

- Delivered part quality performance (PPM)
- Customer disruptions including field failures
- Delivery schedule performance including premium freight
- Customer notifications related to product quality or delivery issues.

PMMCO monitors the performance of the manufacturing processes for product quality and efficiency.



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Reference: SOP: 8.5.1-01, Continual Improvement

Reference: SOP: 5.6-01, Management Review

### 8.2.2 INTERNAL AUDIT

PMMCO conducts internal audits of the Management System at planned intervals to determine:

- a. Conformance to the planned arrangements identified in paragraph 7.1, requirements of ISO/TS 16949:2009 and the PMMCO Management System requirements
- b. The effectiveness of its implementation and maintenance.

PMMCO maintains a procedure for Internal Auditing to ensure the following:

- a. Planning of the internal audit program is based on the status and importance of the processes areas to be audited and results of previous audits
- b. Audit criteria, scope frequency are defined
- c. Selection of Internal Auditor assignments ensures objectivity and impartiality. Auditors do not audit their own work
- d. Responsibilities for planning, conducting, reporting, recording and maintaining records are defined.

Department Managers are responsible to eliminate nonconformances and complete corrective actions in a timely manner. Follow-up audits to verify the effectiveness of corrective action, are conducted documented and reported.

Reference: SOP: 8.2.2-01, Internal Audit

#### 8.2.2.1 Quality Management System Audit



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Audits include the Quality Management System's conformance with ISO/TS 16949:2009 and any additional Quality Management System Requirements.

### **8.2.2.2 Manufacturing Process Audit**

PMMCO maintains a procedure to evaluate the effectiveness of each manufacturing process.

Reference: SOP: 8.2.2-02, Layered Process Auditing

Reference: SOP: 8.5.1-01, Continual Improvement

### **8.2.2.3 Product Audit**

PMMCO audits product at appropriate stages in the manufacturing process from receipt of raw material through shipping to the customer.

Reference: 8.2.4 of this Manual

### **8.2.2.4 Internal Audit Plans**

PMMCO Internal Audits cover the entire Management System, activities and shifts. Audits are conducted based on a calendar year plan. Audit frequencies are evaluated based on internal/external nonconformance's and customer complaints.

Reference: SOP: 8.2.2-01, Internal Audits

### **8.2.2.5 Internal Auditor Qualification**

All auditors are qualified to audit ISO/TS 16949, **ISO 19011 and the process approach to auditing** as specified in the auditing procedures.

## **8.2.3 MONITORING AND MEASUREMENT OF PROCESSES**



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PMMCO maintains a procedure to monitor and measure processes of the Management System to ensure that planned results are achieved. When planned results are not achieved, correction and corrective action is taken as appropriate, to ensure conformity of the product.

Reference: SOP: 8.2.3-01, Process Monitoring

### **8.2.3.1 Monitoring and Measuring of Manufacturing Processes**

PMMCO conducts preliminary process capability studies for each internal or Customer designated special characteristic. Reaction plans identified in the Control Plan are initiated for characteristics that are unstable or non-capable.

PMMCO maintains process capability as approved during the PPAP process by ensuring that the following aspects of the Control Plan and Process Flow are implemented and adhered to:

- Measurement Technique
- Inspection Frequency
- Acceptance criteria
- Reaction plans when the acceptance criteria is not met

Reference: SOP: 8.1-01, Statistical Techniques

Reference: SOP: 8.2.3-01, Process Monitoring

### **8.2.4 MEASUREMENT AND MEASUREMENT OF PRODUCT**

PMMCO maintains procedures to monitor and measure product characteristics at various stages in the manufacturing process, according to planned arrangements, to verify that product requirements have been met.

Reference: SOP: 7.4.3-01, Receiving Purchased Materials and Services

Reference: SOP: 8.2.4-01, Inspection and Testing



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Inspection Records providing evidence of conformity are maintained. Records indicate the employee/s authorizing the release of product.

PMMCO does not release product for delivery until all sequences have been satisfactorily completed, unless authorized by the customer.

#### **8.2.4.1 Layout Inspection and Functional Testing**

PMMCO conducts layout inspections and functional verifications to applicable customer engineering material and performance standards for each product as specified in the control plan. Records are available for customer review.

#### **8.2.4.2 Appearance Items**

Not applicable at this time.

### **8.3 CONTROL OF NONCONFORMING PRODUCT, PROCESSES, AND CONDITIONS**

PMMCO maintains a procedure to ensure that product which does not conform to product or process requirements is identified and controlled to prevent unintended use or delivery. The procedure describes the responsibility and authority for control and disposition of nonconforming product.

PMMCO methods of disposition of nonconforming product include one or more of the following:

- a. Taking action to eliminate the detected nonconformance
- b. Authorizing the use, release or acceptance under concession (deviation) by the customer



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c. Scrap to preclude use or application (discard)

The types of nonconformance's and actions taken, including concessions, are recorded.

All nonconforming products that are reworked or repaired are inspected to ensure conformity to specifications. PMMCO will take appropriate action whenever nonconforming product is detected after delivery or use has started.

Reference: SOP: 8.3-01, Control of Nonconforming Product

### 8.3.1 CONTROL OF NONCONFORMING PRODUCT – SUPPLEMENTAL

Product with unidentified or suspect status will be classified as nonconforming product.

Reference: SOP: 8.3-01, Control of Nonconforming Product

### 8.3.2 CONTROL OF REWORKED PRODUCT

PMMCO maintains a procedure to ensure that employees conducting rework have work instructions including re-inspection requirements.

### 8.3.3 CUSTOMER INFORMATION

Customers are promptly notified of any shipment of nonconforming product.

### 8.3.4 CUSTOMER WAIVER

PMMCO procedures require a customer deviation be obtained prior to shipping when product or manufacturing process is different from that which is currently approved. The following applies to all deviations:



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- a. Maintain a record of the expiration date or quantity authorized
- b. Properly identify each container of deviated product when shipping to the customer
- c. Ensure compliance with the original specifications when deviation expires.

Reference: SOP: 8.3-01, Control of Nonconforming Product

#### **8.4 ANALYSIS OF DATA (Management Review)**

PMMCO maintains a procedure for review of the Management System. The procedure identifies responsibilities to:

- a. Determine, collect and analyze appropriate data to evaluate the suitability and effectiveness
- b. Evaluate data generated as a result of monitoring, measurement and other relevant sources
- c. Evaluate where continuous improvement of the effectiveness of the system can be made.

Analysis of data provides information relating to:

- a. Customer satisfaction
- b. Conformity to product requirements
- c. Characteristics and trends of processes and products including opportunities for Preventive Action.

##### **8.4.1 ANALYSIS AND USE OF DATA**

Comparison of trends to the System Objectives is part of the analysis of data. The comparison leads to:



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- a. Development of priorities for prompt solution to customer-related problems
- b. Determination of key customer-related trends and correlation for status review, decision-making and longer term planning
- c. An information system for the timely review of product information arising from usage

## **8.5 IMPROVEMENT**

### **8.5.1 CONTINUAL IMPROVEMENT**

PMMCO continually strives to improve the effectiveness of the Management System with Quality Policies and Objectives, audit results, analysis of data, corrective and preventive actions and management reviews.

Reference: SOP: 8.5.1-01, Continual Improvement

#### **8.5.1.1 Continual Improvement of the Organization**

The continual improvement process is described in the previous section.

#### **8.5.1.2 Manufacturing Process Improvement**

Reduction of variation and process parameters and increasing the efficiency of the process is the focus of the manufacturing process improvement.

### **8.5.2 CORRECTIVE ACTION**

PMMCO maintains procedures to eliminate the cause of nonconformances in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformance. Procedures define requirements for:

- a. Reviewing nonconformance's



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- b. Determining the causes of nonconformance's
- c. Evaluating the need for action to ensure that nonconformance's do not recur
- d. Determining and implementing action needed
- e. Records of actions taken are maintained
- f. Corrective Action review is accomplished.

Reference: SOP: 8.5.2-01, Corrective Action

#### **8.5.2.1 Problem Solving**

PMMCO corrective action procedures contain a defined process for problem solving leading to root cause identification and elimination. When a customer prescribes a format, that format will be used.

#### **8.5.2.2 Error Proofing**

PMMCO corrective action procedures use error-proofing methods.

#### **8.5.2.3 Corrective Action Impact**

PMMCO corrective action procedures address application to similar processes and products the corrective action and controls implemented, to eliminate the potential for nonconformances.

Reference: SOP: 8.5.2-01, Corrective Action

#### **8.5.2.4 Rejected Product Test/Analysis**

PMMCO maintains a procedure to immediately analyze customer returned product. Records of the tests are maintained and available to the customer upon request. Corrective Action is initiated to prevent recurrence.



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MANUAL

Supersedes:  
12/02/08

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Reference: SOP: 8.5.2-01, Corrective Action

### 8.5.3 PREVENTIVE ACTION

PMMCO maintains a procedure for preventive action to eliminate the causes of potential nonconformances. Preventive Action is appropriate to the effects of the potential problem. The procedure defines the requirements for:

- a. Determining potential nonconformance's and their causes
- b. Evaluating the need for action to prevent occurrence of nonconformance's
- c. Determining and implementing action needed
- d. Records of results of actions taken are maintained
- e. Reviews of preventive action taken.

Reference: SOP: 8.5.3-01, Preventive Action



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It is the responsibility of the reader to review the revisions to this document listed below.

Contact the Originator listed in the heading for further clarification, if necessary.

Date	Description of Change
10/23/06	RELEASE
7/31/07	Updated Management Rep.
2/11/08	Removed Environmental references, add Livonia Site
4-11-08	Page 8 The Mgmt system doc masterlist is maintained by the Quality mgmt Coordinator changed to "Quality System Coordinator"
11-26-08	New Warehouse address was updated, Removed Livonia Site and QMS Rep for Livonia. Page 29 under ref doc changed to SOP: 7.4.1-01 Purchasing & Supplier Qualification. Page 30 under ref doc changed to SOP: 7.4.1-01 Purchasing & Supplier Qualification
12/2/08	Re-numbered turtles Process Matrix and change turtle numbers
11/02/2010	Page 8 The Mgmt system doc masterlist is maintained by the "Quality System Coordinator" changed to "Quality Systems manager. Change TS16949:2002 to 2009