PML, Inc.
Quality Assurance Manual

General Information and Approvals

SCOPE:

PML, Inc. is committed to customer satisfaction, excellence of our products and services, and continual improvement. To realize these objectives, we have implemented and will maintain a quality system that meets the requirements of ISO 9001:2015 and IATF16949:2016.

Our scope of registration is:
The manufacturer of injection molded and extruded rubber components.

Exclusion: PML, Inc does not perform product design and/or embedded software. This responsibility is outsourced to Marugo Rubber Industries.

PML receives all specifications from customers for product design.

PML, Inc. does not produce or process materials, from external providers, containing embedded software.

RESPONSIBILITIES:

The IATF16949 Management Representative maintains the Quality System Manual. The process for updating the Quality System Manual and methods for determining the revision history are detailed in the Log of Revisions of the Quality Manual.

DISTRIBUTION:

PML, Inc. electronically accesses the Quality System Manual. Printed copies are for reference only. The methods for control and distribution are explained in the Log of Revisions in the Quality Manual.

APPROVAL:

PML, Inc. records the revision level, issue date and authorized functions in the Quality System Manual. The Quality Manager approves policy changes to the Quality System Manual. The Registrar is informed in writing of significant changes to the Quality System.

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LOG OF REVISIONS

The IATF16949 Management Representative will process all authorized changes, issue copies for distribution, where appropriate, and ensure any obsolete copies are destroyed. The Master Copy of this quality manual, kept in the custody of the IATF Management Representative, shall be the final authority as to revision status for all sections in the manual.

Date	Rev. Level	Section	Details	Prep By:	Checked By:	Approved By:
07-28-04	A	All	Original Issue			
01-04-06	B	6.2.2.4	See DCR #06-0003			
09-04-08	C	Page 4	See DCR #08-0029			
8-18-09	D	Page 4	See DCR #09-0023			
05-11-10	E	5.0 & Scope	See DCR #10-0026			
04-19-11	F	2	See DCR #11-0010			
10-19-11	G	9	See DCR #11-0057			
10-11-12	H	Appendix	See DCR #12-0037			
07-06-15	I	All	See DCR #15-0020			
07-27-16	J	All	See DCR #16-0015			
07-19-18	K	All	See DCR #18-0022			
08-9-18	L	6.2 & 6.3	See DCR #18-0029	Ira Greer	Pat Barrow	Kristen Carper
5-19-20	M	Scope & Process Matrix	See DCR #20-0013	Kristen Carper	Pat Barrow	Ira Greer
5-25-21	N	Page 5	See DCR #21-0010	Kristen Carper	Maegan Stubblefield	Ira Greer
5/25/23	O	Page 43	See DCR #23-0007	Kristen Carper	Lisa Shawhan	Ira Greer

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Section I: Presentation of the Company

PML, Inc.
75 County Home Road
Paris, Tennessee

PML, Inc. is a privately held subsidiary of Marugo Rubber Industries of Japan and is a manufacturer of extruded hose and tubing, injection molded rubber components, and rubber to metal vibration isolation products.

Manufacturing excellence and continuous improvement are the top operating priorities at PML, Inc. The quality system is designed to ensure that quality is built into the product by utilizing advanced product planning and manufacturing stability and control.

PML, Inc. will maintain and continually improve the Quality System to ensure that our customers' expectations are met or exceeded.

Section II: Organization of the Company

Responsibility for quality rests with every associate at PML, Inc. PML, Inc. defines and documents descriptions for personnel who manage, perform and verify work affecting quality in a job description format. The interrelation of personnel affecting quality is represented on the PML, Inc. organization chart. PML, Inc. designates key responsibilities as follows:

Executive Management – President, Vice Presidents and Directors have the responsibility and authority to set the business objectives, quality goals, operational goals and other required goals for the organization.

Quality Improvement Committee – President, Vice Presidents, Directors and/or other designated representatives have the responsibility and authority for guiding and assisting departments in the implementation of the quality goals and compliance to IATF16949.

Quality Manager – has the responsibility to maintain the quality management system and the authority to institute corrective and preventive action and procedures consistent with the quality goals. Serves the company as the IATF16949 management representative and as the customer representative.

Vice-President of Sales/Purchasing, Engineering Manager, Quality Manager and the Senior Material Engineer – have the responsibility to review contracts and confirm specifications, including special characteristics, with the customer.

Vice-President of Sales/Purchasing – is responsible for purchasing materials that meet the requirements established by the quality system and tracking the performance of suppliers. This

individual or their designate is also responsible for customer portals and receipt of customer scorecards.

Vice-President of Manufacturing/Engineering – is responsible for producing products on-time, to customer specifications and related capacity analysis. Manufacturing is responsible for reducing variation and has the authority to initiate corrective and preventive action that will result in the elimination of non-conforming product.

Maintenance Manager – is responsible for machine/equipment maintenance and the total preventive maintenance system to ensure equipment functions and minimal down times.

Director of Human Resource – is responsible for the training activities, employee communications, associate safety and resources to meet the quality system requirements.

Vice-President of Sales/Purchasing and the Logistics Manager – are responsible for all logistic services to customers and from suppliers.

Vice-President of Manufacturing/Engineering, Engineering Manager, Quality Manager, Material Manager, Director of H.R., Manufacturing Managers and the Maintenance Manager - are responsible for process design, including process safety, and related training requirements.

Top Management, Managers, Supervisors, QC Technicians – are authorized to stop shipments.

In the event of absence or abnormal conditions, an appointed designee will maintain and oversee the process and responsibilities of the assigned process owner.

Section III: Terms and Definitions

8D – Multiple step Problem Solving System

5S – Simplify, Systemize, Sanitize, Standardize, Support

AIAG – Automotive Industry Action Group

APQP – Advanced Product Quality Planning

CPK – Measure of Process Capability

CMM – Coordinate Measuring Machine

EDI – Electronic Data Interchange

EMS – Environmental System Management

FIFO – First In First Out

FMEA – Failure Mode and Effect Analysis

R & R – Repeatability & Reproducibility

ISO – International Standards Organization

MSA – Measurement Systems Analysis

MRO – Maintenance, Repair and Operations

PPAP – Production Part Approval Process

PPM – Parts per Million Defects

QMS – Quality Management System

RFQ – Request for Quote

SDS – Safety Data Sheet

SPC – Statistical Process Control

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Section IV: The Context of PML, Inc.

4.1 Understanding PML, Inc. and its context.

PML, Inc. determines the external and internal issues that are relevant to its purpose, strategic direction and that affects its ability to achieve the intended results of its QMS. PML, Inc. will continue to monitor and update these issues as required. Current issues identified include, but are not limited to, the following:

a) Competitors;
b) Customers;
c) Evolving automotive requirements involving rubber hoses, bushings, anti-vibration products, etc.;
d) Governmental requirements including, but not limited to, personnel safety requirements, product requirements, local government requirements, etc.;
e) Evolving manufacturing technologies, and
f) Other issues as determined relevant by PML, Inc.

Process owners will analyze external and internal issues and update them accordingly. These issues will be reviewed during management review activities and the semi-annual executive meetings and appropriate actions will be taken to address them as required.

4.2 Understanding the Needs and Expectations of Interested Parties.

When the relevant parties are identified, PML, Inc. determines what products, services, information and or data needs to be provided to them or provided to PML, Inc. by them. These relevant interested parties and their expectations are reviewed as necessary by process owners and reported in the management review sessions and semi-annual executive meetings.

4.3 Determining the Scope of the Quality Management System.

PML, Inc. determines and reviews the scope of the QMS by reviewing and analyzing the products and services provided to our customers, the external and internal issues that affect our ability to meet the intended results of the QMS, needs and expectations of all identified interested parties and remote support required by PML, Inc. Based on these results, PML, Inc. determines the required scope of the QMS.

PML, Inc. has established and will maintain this quality manual, including reference to the documented procedures established for the QMS. The controlled copy is maintained by the IATF16949 Management Representative and all other copies are uncontrolled and are for reference only.

4.3.1 Determining the Scope of the Quality Management System - Supplemental.

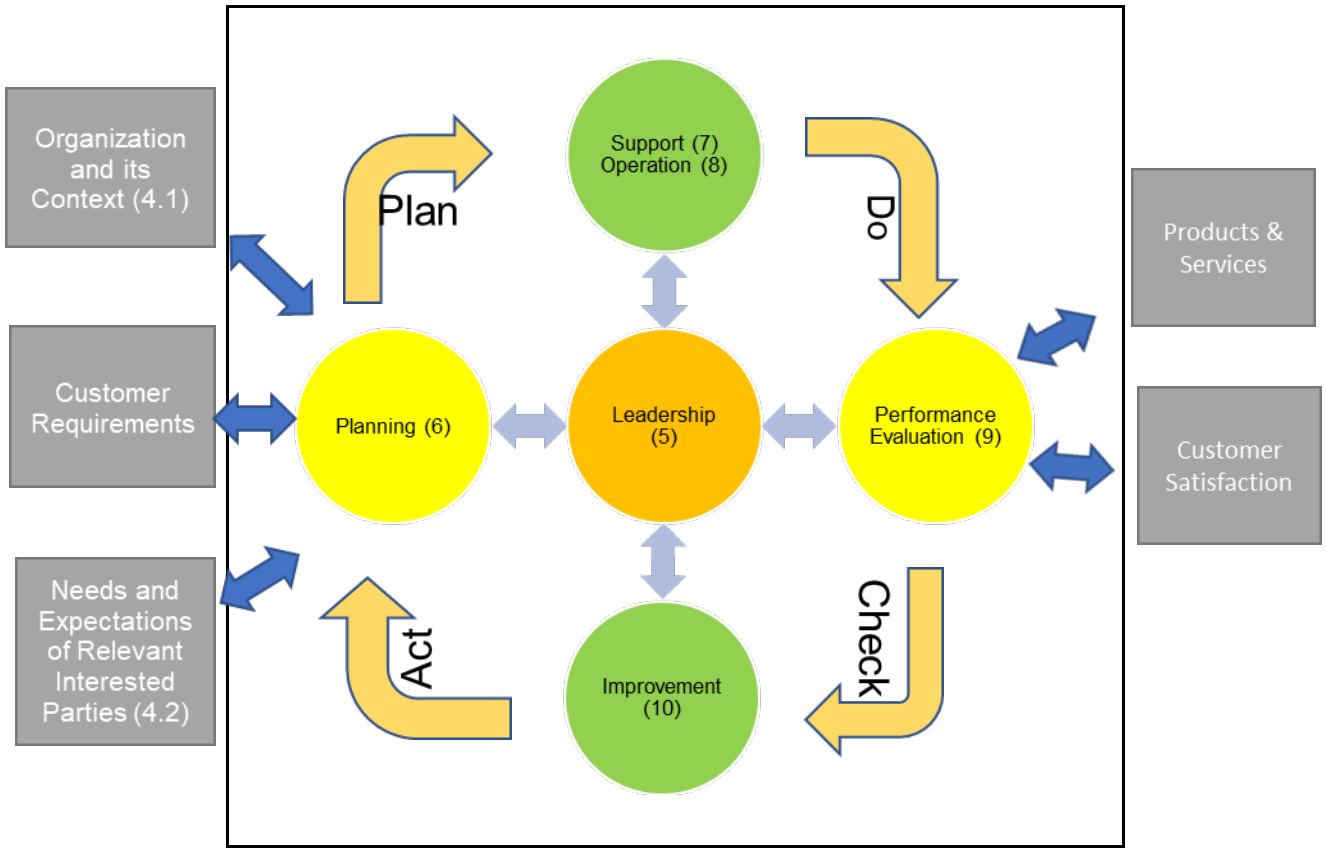
The scope of the QMS covers all relevant processes and activities to manufacture injection molded and extruded rubber components while maintaining compliance with IATF16949:2016, ISO9001:2015 and other relevant compliance standards.

The only exclusions to this manual are in relation to product design and embedded software. PML, Inc. is not product design responsible nor does PML, Inc. supply any products with embedded software requirements.

4.3.2 Customer-Specific Requirements

Specific customer requirements are determined through APQP activities, contract review, customer quality manuals, etc. These requirements are identified in the **Specific Customer Requirement Matrix**.

MODEL OF THE PLAN-DO-CHECK-ACT BASED QUALITY MANAGEMENT SYSTEM USED BY PML, Inc.



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Listed below are the processes identified by PML, Inc.

Customer Oriented Processes

- Market Analysis
- Bid/Quote
- Production
- Shipping / Receiving
- Delivery
- Post Sales/Customer Feedback

Support Processes

- APQP / Program Management – Error prevention
- Document Control
- Purchasing / Supplier Management
- Customer Approval Process (PPAP)
- Human Resource – Training, Safety, Competence
- Maintenance of Equipment, Preventative Maintenance
- Engineering – Tooling, Engineering Specifications, Process Design
- Control of Monitoring & Measuring Devices
- QC – Identification, Traceability, Control of Reworked, Repaired and Non-Conforming Products
- Information System
- Control of Reworked, Repaired and Non-Conforming Products

Management Oriented Processes

- Management Review
- Internal Audit Program
- Monitoring, Measuring & Analysis
- Continuous Improvement (Kaizen)
- Corrective & Preventive Action
- Customer Satisfaction
- Problem Solving

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The table below shows the interactions between PML, Inc.'s Customer processes and support processes

	Market Analysis	Bid/Quote	Production Regular Extrusion	Production THV Extrusion	Production Mixing	Production Rubber to Metal Molding	Production All Rubber Molding	Shipping / Receiving	Delivery	Post Sales / Customer Feedback
APQP/ Program Mgt		X	X	X	X	X	X			X
Document Control	X	X	X	X	X	X	X	X	X	X
Purchasing/ Supplier Mgt.		X								
Customer Approval (PPAP)			X	X	X	X	X		X	X
Human Resources	X	X	X	X	X	X	X	X	X	X
Maintenance / Preventive Maintenance			X	X	X	X	X			
Tooling - Engineering			X	X	X	X	X			
Control of Monitoring & Measuring Devices			X	X	X	X	X			
QC		X	X	X	X	X	X	X	X	X
Information Systems	X	X	X	X	X	X	X	X	X	X

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		Process Interaction Matrix																			
		Processes Audited																			
Section Title / Number	**Responsible Party(s)**	**Procedure**	**Exclusion**	**Top Management / Management Review**	**Internal Audit**	**Corrective / Preventive Action**	**Human Resources**	**Sales / Customer Service**	**Purchasing**	**Information Technology**	**Program (APQP)**	**PPAP**	**Quality Control / Customer Satisfaction**	**Engineering**	**Maintenance**	**Production Control**	**Regular Extrusion**	**THV Extrusion**	**Mixing**	**Rubber to Metal Bonding Molding**	**All Rubber Molding**	**Shipping / Receiving**
4.1 Understanding the organization and its context	Top Management			**P**			S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S
4.2 Needs and expectations of interested parties	Top Management			**P**			S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S
4.3 Determining the scope of the QMS	Top Management			**P**									S									
4.4 Quality management system and its processes	Top Management			**P**			S	S	S		S	S	S	S	S	S	S	S	S	S	S	S
4.4.1.2 - Product Safety.	Assist. QC Manager	X		S			S	S	S		S	S	**P**	S	S	S	S	S	S	S	S	S

5.1.1 Leadership - General	Top Management			**P**																	
5.2 Policy	Top Management			**P**			S						S								
5.3 Organizational roles, responsibilities and authorities	Top Management			**P**			S	S			S		S								
6.1 Actions to address risks and opportunities	Top Management			**P**			S	S	S	S	S		S	S	S	S	S	S	S	S	S
6.1.2.2 - Preventive Action	Assist. QC Manager	X					S	S	S	S	S		**P**	S	S	S	S	S	S	S	S
6.1.2.3 - Contingency plan	Top Management			**P**			S	S	S	S	S		S	S	S	S	S	S	S	S	S
6.2 Quality objectives and planning	Top Management			**P**			S		S		S		S	S	S	S	S	S	S	S	
6.3 Planning of changes	Program Management			S	S	S	S	S	S	S	**P**	S	S	S	S	S	S	S	S	S	S
7.1.1 Resources - General	Top Management			**P**			S						S	S	S						
7.1.2 People				S			**P**	S	S		S		S	S	S	S	S	S	S	S	

7.1.3 Infrastructure	Top Management			**P**						S	S		S	S	S	S	S	S	S	S	S	
7.1.4 Environment for the operation of processes	Top Management			**P**									S	S	S	S	S	S	S	S	S	
7.1.5.1 - Monitoring and Measuring Resources - General	Top Management			**P**			S		S		S		S	S	S	S	S	S	S	S	S	
7.1.5.2 - Measurement Traceability	Assist. QC Manager									S	S	S	**P**	S	S	S	S	S	S	S	S	
7.1.5.2.1 - Calibration / Verification Records	Assist. QC Manager	X								S	S	S	**P**	S	S	S	S	S	S	S	S	
7.1.5.3 Laboratory Requirements	Assist. QC Manager	X							S			S	**P**	S	S	S	S	S	S	S	S	
7.1.6 Organizational knowledge	Top Management			**P**			S	S	S	S	S		S	S	S	S	S	S	S	S	S	
7.2 Competence	Human Resource Director	X		S			**P**	S	S	S	S		S	S	S	S	S	S	S	S	S	
7.2.3 - Internal Auditor Competency	Assist. QC Manager	X					S						**P**									
7.3 Awareness	Top Management			**P**			S	S	S	S	S		S	S	S	S	S	S	S	S	S	

7.4 Communication	Top Management			P			S	S	S	S	S		S	S	S	S	S	S	S	S	S	
7.5 Documented information	Assist. QC Manager	X		S	S		S	S	S	S	S	S	P	S	S	S	S	S	S	S	S	S
7.5.1.1 - Quality Management System Documentation	Assist. QC Manager	X		S	S		S	S	S	S	S	S	P	S	S	S	S	S	S	S	S	S
7.5.3.2.2 - Engineering Specifications	Engineering Manager	X						S			S	S	S	P	S		S	S	S	S	S	
8.1 Operational planning and control	Top Management			P			S	S	S	S	S		S	S	S	S	S	S	S	S	S	S
8.2 Requirements for products and services	Program Management			S			S	S	S	S	P	S	S	S	S	S	S	S	S	S	S	S
8.2.1 Customer communication	VP Sales & Purchasing			S				P			S	S	S									
8.2.2 Determining product/service requirements	VP Sales & Purchasing	X					S	P	S	S	S		S	S	S	S	S	S	S	S	S	S
8.2.3 Review of requirements related to products and services	VP Sales & Purchasing	X					S	P	S	S	S	S	S	S	S	S	S	S	S	S	S	S
8.2.4 Changes to requirements for products and services	VP Sales & Purchasing							P	S	S	S	S	S	S	S	S	S	S	S	S	S	S

8.3.2.2 - Product design skills			X																		
8.3.2.3 - Development of Products with Embedded Software			X																		
8.3.3.1 - Product Design Input			X																		
8.3.3.2 - Manufacturing Process Design Input	Engineering Manager	X		S			S	S	S	S	S	S	S	**P**	S	S	S	S	S	S	S	S
8.3.5 - Design and Development Outputs			X																		
8.3.5.2 - Manufacturing process design output	Engineering Manager	X		S			S	S	S	S	**P**		S	S	S	S	S	S	S	S	S	S
8.4 Control of externally provided processes, products/services	VP Sales & Purchasing	X		S				S	**P**		S	S	S									
8.5.1 Control of production and service provision	Top Management			**P**			S	S	S	S	S		S	S	S	S	S	S	S	S	S	S
8.5.1.5 - Total Productive Maintenance	Maintenance Manager	X					S		S	S	S		S	S	**P**	S	S	S	S	S	S	S
8.5.1.6 - Management of Production Tooling,	Engineering Manager	X								S	S		S	**P**	S	S	S	S	S	S	S	S

Manufacturing, Test, Inspection Tooling and Equipment																					
8.5.2 Identification and traceability	Assist. QC Manager	X							S	S			**P**	S	S	S	S	S	S	S	S
8.5.3 Property belonging to customers or external providers	VP Sales & Purchasing							**P**				S	S	S	S	S	S	S	S	S	S
8.5.4 Preservation	Assist. QC Manager								S			S	**P**			S	S	S	S	S	S
8.5.5 Post-delivery activities	VP Sales & Purchasing							**P**		S			S	S	S	S	S	S	S	S	S
8.5.6 Control of changes including design 8.3.6	Engineering Manager	X						S	S	S	**P**	S	S	S	S	S	S	S	S	S	S
8.6 Release of products and services	Assist. QC Manager										S	S	**P**	S		S	S	S	S	S	
8.7 - Control of nonconforming outputs	Assist. QC Manager	X				S			S				**P**	S	S		S	S	S	S	S
8.7.1.2 - Control of Non-Conforming Outputs	Assist. QC Manager	X				S			S				**P**	S	S		S	S	S	S	S
8.7.1.4 - Control of Rework	Assist. QC Manager	X				S			S				**P**	S	S		S	S	S	S	S

9.1.1 Monitoring and measurement - General	Assist. QC Manager			S			S	S	S	S	S	S	P	S	S		S	S	S	S	S	S
9.1.2 Customer satisfaction	VP Sales & Purchasing			S				P		S	S		S									
9.1.3 Analysis and evaluation	Top Management			P			S		S	S	S		S	S	S	S	S	S	S	S	S	S
9.2 Internal audit	Assist. QC Manager	X		S	S	S	S	S	S	S	S	S	P	S	S	S	S	S	S	S	S	S
9.3 Management review	Top Management	X		P									S									
10.1 Improvement - General	Top Management			P	S		S	S	S	S	S		S	S	S	S	S	S	S	S	S	S
10.2 Nonconformity and corrective action	Assist. QC Manager	X		S	S	S	S		S	S	S	S	P	S	S	S	S	S	S	S	S	S
10.2.4 - Error Proofing	Engineering Manager	X			S	S				S	P	S	S	S	S	S	S	S	S	S	S	S
10.3 Continual improvement	Engineering Manager	X		S	S	S	S	S	S	S	S	S	S	P	S	S	S	S	S	S	S	S

P - Primary Responsibility
S - Secondary Responsibility

4.4 Quality Management System and Its Processes

4.4.1 General Requirements

PML, Inc. shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard. The organization shall determine the processes required, their application throughout the organization and shall:

a. Determine the inputs required and the outputs expected from these processes;
b. Determine the sequence and interaction of these processes;
c. Determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
d. Determine the resources needed for these processes and ensure their availability;
e. Assign the responsibilities and authorities for these processes;
f. Address risks and opportunities as determined in accordance with the requirements of Section 6.1, and
g. Evaluate the processes and implement any changes needed to ensure these processes achieve their intended results and are continually improved.

4.4.1.1 Conformance of Products and Processes.

It is the responsibility of each PML, Inc. associate to ensure that all products and services conform to the specified customer requirements, including service parts and those that are outsourced, and to ensure that all statutory and regulatory requirements are adhered to.

4.4.1.2 Product Safety

PML, Inc. has documented processes for the management of product-safety related products and manufacturing processes. These processes are identified in the ***Product Safety Management Level II Procedure.***

4.4.2 General Requirements

The quality system manual, referenced procedures, work instructions and records of evidence comprise PML, Inc.'s quality system. The quality system manual covers the requirements of the International standards; ISO9001:2015 and IATF16949:2016. The structure of the quality system is as follows:

- Level 1 - Quality Systems Manual
- Level 2 - Procedures
- Level 3 - Work Instructions and Process Instructions
- Level 4 – Records (Reports, Tags, Miscellaneous Documents)

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Section V: Leadership and Commitment

5.0 Leadership

5.1 Leadership and Commitment

5.1.1 General

PML, Inc.'s top management shall provide evidence of its commitment and accountability to the development and implementation of the quality management system and continually improving its effectiveness and efficiency by:

a. Ensuring the context and strategic direction of PML, Inc. is determined and communicated to the relevant interested parties;
b. Communicating to all associates the importance of meeting customer and legal requirements;
c. Establishing and communicating the quality policy and quality objectives;
d. Conducting management reviews;
e. Ensuring the availability of resources through the business planning process;
f. Promote the use of process approach and risk-based thinking, and
g. Supporting relevant management roles to demonstrate and reinforce their leadership as it applies to their areas of responsibility.

5.1.1.1 Corporate Responsibility

PML, Inc. realizes that to be a successful company, all associates must be forthright, honest and fair in their dealings with all interested parties whether customers, suppliers, workforce, local community, etc. To ensure such conduct it will:

a. Communicate that bribery, of any type or amount, is strictly forbidden;
b. Provide a PML associate handbook to all associates that communicates all rules and policies of PML, Inc. The handbook is available via the PML, Inc. website and by hard copy, if desired;
c. Communicate to all associates the method for communicating a violation of any code of conduct and that there will be no disciplinary action taken for communicating a good-faith belief that a violation has occurred;
d. PML, Inc. will always make our associates safety our number one priority in any and all activities that are pursued, and
e. PML, Inc. will always treat our associates with respect and dignity.

5.1.1.2 Process Effectiveness and Efficiency

Top management will the key process indicators of all product realization processes and support processes to ensure their effectiveness and efficiency.

5.1.1.3 Process Owners

Top management shall identify process owners, whether product realization or support, and communicate responsibilities and goals targeted for each process. To ensure this is effectively accomplished, PML, Inc. will do the following:

a. The management structure shall be documented and communicated by use of an organizational chart;
b. Ensure responsibilities are communicated through job descriptions, and
c. Ensuring competency by determining and documenting the successful completion of the required education, experience and or training.

5.1.2 Customer Focus

Top management will ensure that customer and legal requirements are determined and achieved with the aim of enhancing customer satisfaction. These requirements are communicated by the PML, Inc. sales department throughout the organization. Multidisciplinary teams meet regularly to review customer requirements, determine risks and opportunities and ensure customer satisfaction is enhanced.

5.2 Quality Policy

5.2.1 Establishing the Quality Policy

Through quarterly plant meetings, as well as scheduled management review meetings, PML, Inc.'s top management will ensure that the quality policy:

a. Is appropriate to the purpose of PML, Inc.;
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;
d. Is communicated and understood within PML, Inc., and
e. Is reviewed for continuing suitability.

5.2.2 Communicating the Quality Policy

To ensure proper communication is achieved, PML, Inc will:

a. Inform associates of the quality policy during their orientation with the human resource department;
b. Post signs throughout the facility stating the quality policy, and
c. Ensure communication of the quality policy to all relevant interested parties.

PML Inc.'s quality policy is to provide our customers defect-free products, on time, at a competitive price with a commitment to continuous quality improvement.

5.3 Organization Roles, Responsibilities and Authorities

Top management has defined responsibilities and authorities. These are communicated through organizational charts, Section II of the quality manual, and through job descriptions for each job function. Each process owner will report the results and opportunities of their specific areas during quarterly management reviews, daily QCD meetings, etc. to top management. PML, Inc. will ensure the integrity of the QMS is maintained when changes are planned and implemented.

5.3.1 Organization Roles, Responsibilities and Authorities – Supplemental

Top management has designated the Quality Manager and the responsible process owner as the individuals with the responsibility and authority to ensure that customer requirements are addressed. This includes selection of special characteristics, setting quality objectives, related training, corrective and preventive actions, product development, capacity analysis, logistics information, customer scorecards, customer portals and process design and development.

5.3.2 Responsibility and Authority for Product Requirements and Corrective Actions.

Managers with responsibility and authority for corrective action will be promptly informed of products or processes which do not conform to requirements. **All associates are responsible for product quality and have the authority to stop production to correct quality problems.**

Production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring product quality and stopping shipment, if required. ***See Corrective Action Level II Procedure.***

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Section VI: Planning

6.1 Actions to Address Risk and Opportunities

6.1.1 & 6.1.2 General Information

Planning for the quality management system and business plans are carried out by the following steps:

a. Consideration is given to the external and internal issues identified in 4.1 and the needs and expectations of the interested parties identified in 4.2;
b. Analysis of competitive products and benchmarking inside and outside the rubber industry is conducted, when possible;
c. All managers contribute experience, information and suggestions to the development of the business plan and improving the quality management system;
d. Customer performance is analyzed based on trends in current sales, future forecasts, potential opportunities for new business; quality performance, delivery performance and other critical KPI's;
e. Determine the required actions to ensure the successful completion of the required quality management system outputs;
f. Opportunities and risks are identified to enhance the performance of the quality management system. Resources are determined and allocated based on the potential impact of the identified risks and opportunities. These data also drive preventive action activities. ***(Refer to Preventive Action Level II Procedure)***
g. Actions are determined to reduce defect, waste and other undesirable outcomes;
h. Effectiveness and efficiency are monitored on a regular basis and actions taken based on these results, and
i. A strategic business plan is developed that includes 1- year and 3 - year projections.

6.1.2.1 Risk Analysis

PML, Inc. will document evidence of risk analysis for lessons learned from:

a. Product recalls;
b. Product audits;
c. Field returns and repairs;
d. Interested party complaints;
e. Excessive overtime;
f. Turnover;
g. Premium freight;
h. Accidents;
i. Scrap,
j. Rework, and
k. Other information as required.

6.1.2.2 Preventive Action

PML, Inc. will determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate for the effects of the potential problems.

PML, Inc. has a documented procedure titled ***Preventive Action Level II Procedure*****,** which defines the 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(s) needed;
d. Records of actions taken and results;
e. Reviewing the effectiveness of the preventive action taken, and
f. Utilizing lessons learned to prevent similar non-conformances in other processes.

6.1.2.3 Contingency Plans

PML, Inc. reviews reasonably foreseeable internal and external risks to all manufacturing processes and infrastructure equipment that are essential to maintain production outputs and meet customer requirements. Contingency plans are documented and reviewed, at a minimum, annually to protect and ensure the supply of product to the customer in the, at a minimum, following events:

a. Interruption from externally provided products, processes and services;
b. Key equipment failures;
c. Reoccurring natural disasters;
d. Fire;
e. Utility interruptions;
f. Labor shortages;
g. Chemical spills;
h. Hazardous releases;
i. Infrastructure disruptions, and
j. Information technology equipment failures.

A notification process is in place to inform all relevant interested parties as to the extent and duration of the situation impacting customer operations. Periodic tests are conducted to test the effectiveness of the contingency plans. If changes are made, a description of the change, why the change occurred and the person authorizing the change shall be documented.

In the event of an unplanned stoppage of production, after re-start is accomplished, product will be validated to ensure it meets customer requirements. This will be accomplished through the 1st piece inspection process.

6.1.2.4 Contingency Planning Acronym

E – List the events that could potentially interfere and or disrupt the ability to supply products in the desired quantity or that could prevent the conformance with required specifications whether internal, customer or governmental. **Evaluate** the impact of each and assign resources based on the evaluation.

R – Focus on those events that could **reasonably** occur. For example, Paris, TN will probably not suffer a volcanic eruption, however, the potential for tornadoes is high.

A – Develop a contingency **action** plan for the likely events. Determine what actions will be Required, **first, to ensure our associates are protected** and then how PML, Inc. will continue to provide our customers defect free products on time. Remember, customer communication is critical. They must be communicated with to ensure their understanding of the situation.

S – The plans will be **simulated** to test the effectiveness of the action plan.

E – Was the plan **effective**? Were the planned results achieved? If so, good. If not, go back and reformulate your action plan. Focus on those areas that fell short of the initial plan. Prioritize and allocate the resources as efficiently as possible.

P – D – C – A

6.2 Quality Objectives & Planning to Achieve Them

6.2.1 General Information

PML will make quality objectives at relevant functions, levels and processes needed for quality management system. The quality objectives shall:

a. Be consistent with the quality policy;
b. Be measurable;
c. Consider applicable requirements;
d. Be relevant to conformity of products and services and to the enhancement of customer satisfaction;
e. Be monitored;
f. Be communicated;
g. Be updated as appropriate.

The organization shall maintain documented information on the quality objectives.

6.2.2 General Information

When PML is planning how to achieve its quality objectives it shall determine:

a. What will be done;
b. What resources will be required;
c. Who will be responsible;
d. When it will be completed;
e. How the results will be evaluated

6.2.2.1 Quality Objectives & Planning to Achieve Them - Supplemental

PML's top management shall ensure that quality objectives to meet customer requirements are defined, established, and maintained for relevant functions, processes, and levels throughout the organization.

The results of PML's review regarding interested parties and the relevant requirements shall be considered when it establishes its annual quality objectives and related performance targets.

6.3 Planning of Changes

Required changes will be controlled, planned and PML shall consider:

a. The purpose of the changes and potential consequences;
b. The integrity of the quality management system;
c. The availability of resources;
d. The allocation or re-allocation of responsibilities and authorities.

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Section VII - Support

7.1 Resources

7.1.1 General

When determining the required resources to implement, maintain and continually improve the quality management system, PML, Inc. will analyze the following:

a. The capabilities and constraints of internal resources, and
b. The resources required from external providers.

Successful completion of the above will strengthen PML, Inc.'s ability to enhance customer satisfaction.

7.1.2 People

PML, Inc. shall determine and provide the necessary people to ensure the effective implementation of the quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

PML, Inc. determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes buildings, workspace, associated utilities, process equipment, hardware, software, transportation resources, information and communication technology and supporting services.

7.1.3.1 Plant, Facility and Equipment Planning

PML, Inc. uses a multi-disciplinary team to develop facilities, processes, and equipment in conjunction with the advanced quality planning process. Consideration is given to risk identification and mitigation methods including, but not limited to, the use of PFMEA's. This allows PML, Inc. to:

a. Improve associate safety;
b. Optimize and synchronize material flow;
c. Improve material handling;
d. Increase the value-added use of existing floor space, and
e. Improve control of non-conforming products.

When launching new products and processes, PML, Inc. shall, using advanced quality planning and lean manufacturing techniques, evaluate, develop and implement manufacturing feasibility studies, including capacity planning. These methods shall also be used for evaluating changes proposed to existing operations.

PML, Inc. shall maintain process effectiveness, including periodic re-evaluation relative to risk, to incorporate any changes made during process approval, control plan maintenance and verification of job set-ups. Assessments of manufacturing feasibility and evaluation of capacity planning shall be inputs to management review.

The above methods shall apply to any on-site supplier of products and services.

7.1.4 Environment for the Operation of Processes

PML, Inc. recognizes the importance of a suitable environment for our associates. Consideration will be given to:

a. Ensuring a safe work environment for all associates;
b. Ensuring discrimination does not occur;
c. Promoting a non-confrontational work environment;
d. Reducing stress to the extent possible;
e. Burn out prevention;
f. Maintaining clean work areas;
g. Reducing noise to the extent possible;
h. Ensuring light is available to the necessary levels, and
i. Maintaining reasonable temperature control for all associates.

7.1.4.1 Environment for the Operation of Processes – Supplemental

PML, Inc. promotes an environment that is clean and in a state of order that is consistent with its products and processes. It is the responsibility of each associate to maintain a clean and orderly work area. By maintaining a clean and orderly environment we not only improve control of the products and processes, but also more importantly increase the level of associate safety.

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

Proper measuring resources are critical to ensure accurate product and process validation. To ensure reliable results when measurements are taken, PML, Inc. shall:

a. Provide the proper resources including equipment and training;
b. Ensure suitability of the specific type of monitoring and measurement activities;
c. Promote the proper maintenance activities for continuing fitness, and
d. Retain appropriate documentation as evidence of the fitness for the intended purpose.

7.1.5.1.1 Measurement System Analysis

Appropriate statistical studies are conducted to analyze the variation present in the different types of measurement systems used for monitoring special characteristics referenced in the control plans. The analytical methods and acceptance criteria conform to the Measurement Systems Analysis reference manual. Other methods and acceptance criteria may be used, if approved by the customer, and additional documentation shall be maintained as evidence of the results of the analysis and acceptance by the customer.

7.1.5.2 Measurement Traceability

When measurement traceability is a customer requirement or is considered by PML, Inc. to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a. Calibrated, verified or both;
b. At specified intervals or prior to use against measurement system standards traceable to international or national measurement standards;
c. When no international or national standards exist, the basis used for calibration or verification shall be retained as documented information;
d. Identified to determine their status, and
e. Safeguarded against adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

When measuring equipment is found to be unfit for its intended purpose and the validity of previous measurement results have been affected, PML, Inc. shall take the appropriate action necessary.

7.1.5.2.1 Calibration/Verification Records

PML, Inc.'s calibration system is governed by the ***Calibration System Level II Procedure.*** Records of calibration / verification activities for all gauges, measuring and test equipment, including employee, customer and on-site supplier owned equipment are used to provide evidence of conformity to internal requirements, legislative and regulatory requirements and customer defined requirements.

PML, Inc. shall ensure the activities and records include the following details:

a. Revisions following engineering changes that affect measurement systems;
b. Any out of spec readings as received for calibration / verification;
c. An assessment of risk of the intended use of the product caused by the out-specification condition;
d. When a piece of inspection measurement and test equipment is found to be out of calibration or defective during its planned verification or calibration or during its use, documented information on the validity of previous measurement results obtained with this piece of inspection measurement and test equipment shall be retained, including the associated standard's last calibration date and the next due date on the calibration report;
e. Customer notification if suspect product or material has been shipped;

f. Statements of conformity to specification after calibration/verification;
g. Verification that the software version used for product and process control is as specified;
h. Records of the calibration and maintenance activities for all gauging (including employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment);
i. Production-related software verification used for product and process control (including software installed on employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment).
j. Work instructions detail the process for the verification of measuring equipment. Calibration records list the equipment description, unique identification, location, frequency of checks, check method, acceptance criteria and standards used. The ***Calibration System Level II Procedure*** explains the actions to be taken when results are unsatisfactory.

7.1.5.3 Laboratory Requirements

7.1.5.3.1 Internal Laboratory

PML, Inc.'s laboratory has a laboratory scope containing the following: (Reference ***Laboratory Requirements Level II Procedure***)

a. The specific tests, evaluations and calibrations PML, Inc. has the ability and competency to perform.
b. A list of the equipment which it uses to perform the above.
c. A list of the testing methods and standards to which it performs the above.

Additionally, the laboratory documents all its policies, systems, programs, procedures, instructions and findings which enable the laboratory to assure the quality of the tests or calibration results it generates within the scope, including those required by the customer.

Laboratory personnel making professional judgments with reference to testing and/or calibration have appropriate background and experience.

PML, Inc.'s laboratory has documented procedures for the receipt, identification, handling, protection and retention or disposal of test samples and/or calibration equipment items, including all provisions necessary to protect the integrity of the items. Items are retained until final data is complete throughout the life of the item in the laboratory.

PML, Inc.'s laboratory monitors, controls and records environmental conditions when required by relevant specifications or where they influence the quality of results. Requirements are established and maintained as appropriate to the technical activities concerned.

PML, Inc.'s laboratory uses test and /or calibration methods, including those for sampling, which meet the needs of the customer and are appropriate for the tests and/or calibrations it undertakes, and they are traceable to the relevant process standard. Before carrying out any such work, the laboratory verifies its capability to perform to the standard specifications. When it is necessary to employ methods not covered by standard specifications, the customer is notified.

Statistical techniques are applied to verification activities whose deliverables are data. Records are reviewed as required.

7.1.5.3.2 External Laboratory

External/commercial/independent laboratory facilities used for inspection, test or calibration services by PML, Inc. will have a defined laboratory scope that includes the capability to perform the required inspection, test or calibration. There will be evidence that the external laboratory is acceptable to PML, Inc. and its customer or the laboratory will be accredited to ISO/IEC 17025 or national equivalent.

7.1.6 Organizational Knowledge

PML, Inc. determines and documents the knowledge necessary for the operation and control of its process to ensure product and service conformity by:

a. Addressing changing knowledge needs and trends;
b. Comparing current knowledge base to future knowledge requirements;
c. Updating knowledge through OJT;
d. Utilizing seminars, periodicals, scholastic and other external training resources;
e. Promoting open communication between all associates to share information, and
f. Promoting involvement in meetings, for example QCD, Quarterly Management meetings, associate meetings, etc., so information can be shared.

7.2 Competence

PML, Inc. will:

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, and
d. Maintain appropriate records of education, training, skills and experience.

7.2.1 Competence – Supplemental

PML, Inc. has established and maintains a documented procedure identifying training needs and achieving competence of all personnel performing activities affecting product quality. Associates performing specific assigned tasks are qualified, as required, with attention to the satisfaction of customer requirements.

7.2.2 Competence – On-The-Job-Training

PML, Inc. provides on the job training for associates in any new or modified job, customer required training, internal required training or legislative requirements affecting product quality, including contract or agency personnel. Associates whose work can affect quality are informed

about the consequences to the customer of nonconformity to quality requirements. The level of detail of on-the-job-training shall be commensurate based on the level of education the personnel possess and the complexity of the task required to be performed. (***Refer to Training Level II Procedure)***

7.2.3 Internal Auditor Competency

PML, Inc. has a documented process to verify that internal auditors are competent including any customer specific requirements. The organization shall maintain a list of qualified internal auditors. ***(Refer to Internal & Second Party Auditor Competency Level II Procedure)***

Quality management system, manufacturing process and product auditors shall be able to demonstrate the competence in:

a. The automotive process approach for auditing, including risk-based thinking;
b. Applicable customer-specific requirements;
c. ISO9001:2015, IATF16949:2016 and other required requirements related to the scope of the audit;
d. Applicable core tool requirements related to the scope of the audit;
e. How to plan, conduct, report, and close out audit findings;
f. The technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis (such as PFMEA) and control plan methodology, and
g. Product requirements and use of relevant measuring and test equipment to verify product conformity.

Where training is provided, documented information shall be retained. Maintenance of and improvement in internal auditor competence shall be demonstrated through:

a. Executing a minimum of 5 audits per year; and
b. Maintaining knowledge of relevant requirements based on internal and external requirements.

7.2.4 Second-Party Auditor Competency

PML, Inc. shall determine the competence of the auditors undertaking the second-party audits. Second-party auditors shall meet customer specific requirements for auditor qualification and demonstrate the following core competencies, including understanding of:

a. The automotive process approach to auditing, including risk-based thinking;
b. Applicable customer and organization specific requirements;
c. Applicable ISO9001:2015 and IATF16949:2016 requirements related to the scope of the audit;
d. Applicable manufacturing process(es) to be audited, including PFMEA and control plan;
e. Applicable core tool requirements related to the scope of the audit,
f. How to plan, conduct, prepare audit reports, and close out audit findings.

7.3 Awareness

PML, Inc. shall ensure that persons doing work under its control are aware of the following points:

a. Required safe work procedures and personal protective equipment;
b. The quality policy;
c. Relevant quality objectives;
d. Their contribution to the effectiveness of the quality management system, including the benefits of improved performance, and
e. The implications of not conforming with the quality management system requirements.

7.3.1 Awareness – Supplemental

PML, Inc. maintains documented training information demonstrating that all employees are aware of their impact on product quality and the importance of their activities in achieving, maintaining, and improving quality, including customer requirements and the risks involved for PML, Inc. and the customer with nonconforming product(s).

7.3.2 Employee Motivation and Empowerment

PML, Inc. has a process to motivate its associates to achieve quality objectives, make continual improvements and create an innovative environment. The process promotes quality and technological awareness throughout the whole company. Some of the motivational techniques used are as follows:

a. QCDS Performance Vacation Day;
b. Monthly treat/recognition if PML, Inc.'s number of quality claims and PPM targets are met for that particular month;
c. Safety incentive days;
d. Safety Lotto;
e. Perfect Attendance – awarded quarterly;
f. QCDS Performance Bonus – Quarterly;
g. OEE performance results, and
h. IATF16949 / ISO9001 / ISO14001 Audit Performance Luncheons.

7.4 Communication

Top management ensures that appropriate communication processes are established within PML, Inc. and that communication takes place regarding the effectiveness of the quality management system. Internal communication includes, but is not limited to, the following activities:

a. Quarterly management meetings – process owners report on key performance indicators.
b. Quarterly associate meetings – updates by top management may include performance indicators, customer updates, policy changes / reinforcement, etc.
c. PML, Inc. newsletter – documented information that focuses on select areas. Generally written by department managers.

d. Pre-shift meetings – held by supervisors /groupleaders and focuses on immediate concerns as they may relate to quality issues, delivery issues, demand fluctuations, safety, etc.

7.5 Documented Information

7.5.1 General

The quality system manual, referenced procedures, work instructions and records of evidence comprise PML, Inc.'s quality system. The quality system manual encompasses the requirements of ISO9001:2015 and IATF16949:2016. The structure of the quality system is outlined below:

a. Level 1 - Quality Systems Manual
b. Level 2 - Procedures
c. Level 3 - Work Instructions and Process Instructions
d. Level 4 – Records (Reports, Tags, Miscellaneous Documents)

7.5.1.1 Quality Management System Documentation

Documented procedures covering the requirements of IATF16949:2016, PML, Inc.'s quality policy and procedures and customer standards define the quality system**.** A controlled numbering system governs all documentation.

The procedures and instructions effectively implement the quality system policies. Work instructions explain how to perform an operation and support system procedures that document the activity, including responsibilities and timing.

7.5.2 Creating and Updating

When documentation is created or updated, PML, Inc. shall ensure:

a. Proper identification and description, including title, date, author, reference number, etc.;
b. Proper format and media, and
c. Review and approval for suitability and adequacy.

7.5.3 Control of Documented Information

7.5.3.1 General Requirements

PML, Inc. maintains documented procedures for the identification, distribution, retrieval, access, storage, maintenance and disposition of records. This is summarized in the ***Quality/Environmental Record Retention Level II Procedure.***

Quality records are maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent subcontractor quality records are included in the retention and maintenance.

The records are legible, stored in a suitable environment to prevent damage or deterioration and are readily retrievable. Electronic data is backed-up and stored. Quality records are made available to the customer or the customer's representative when agreed to contractually.

7.5.3.2 General Requirements – Continued

PML, Inc. has established procedures to control documents required by the quality management system. Customer drawings, standards, documents and data supporting the quality system are reviewed and approved by authorized personnel before issue. Master lists identifying the current revision status of all procedures, work and process instructions, and customer drawings are maintained.

Obsolete documents are promptly removed from all points of issue including operating locations. Obsolete documents are destroyed or identified as "Obsolete" if retained for reference, to assure against unintended use. Where appropriate, electronic media is immediately replaced with updates upon reissue.
Reference the following procedures***: System Documentation and Drawing and Standard Control Level II Procedures.***

These documents will ensure the following:

a. Approved for adequacy prior to use;
b. Accessed, used and retrieved properly;
c. Reviewed and updated as necessary and re-approved;
d. Revision status of documents are identified;
e. Relevant versions of applicable documents are available at points of use;
f. Documents remain legible and readily identifiable;
g. Required documents of external origin are identified and their distribution controlled, and
h. The unintended use of obsolete documents is prevented.

7.5.3.2.1 Record Retention

Reference the ***System Documentation Level II Procedure*** for retention times by record type. Customer specific retention periods are adhered to as contractually required, if not specified by customer the minimum retention time will be the length of time the part is active for production and service requirements plus one calendar year. Documents from superseded parts required for new part qualification are retained in the new part file. The control of records shall satisfy all customer, organizational, statutory and regulatory requirements.

7.5.3.2.2 Engineering Specifications

Customer engineering standards, specifications and changes that affect the product or process are reviewed per the ***Drawing and Standard Control Level II Procedure*** to assure the review, distribution and implementation within ten business days. Implementation includes updates to all appropriate documents.

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Section VIII - Operations

8.0 Operation

8.1 Operational Planning and Control

PML, Inc. plans and develops the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the quality management system. In planning product realization, PML, Inc. determines the following:

a. Quality objectives and requirements for the product;
b. The need to establish processes, documents, controls 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;
e. Ensure planning outputs suitable for operations;
f. Proper control of planned changes;
g. Proper review and mitigation of consequences of unintended changes, and
h. Proper control of outsourced processes.

8.1.1 Operational Planning and Control - Supplemental

PML, Inc. shall use the APQP process for product realization project planning. At a minimum, the following points will be covered:

a. Customer products and technical specifications;
b. Logistics requirements;
c. Manufacturing feasibility;
d. Process design, including lean manufacturing techniques;
e. Acceptance criteria, and
f. Project planning.

8.1.2 Confidentiality

PML, Inc. will ensure confidentiality of customer-contracted products and projects under development, and related product information.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

PML, Inc. utilizes several methods of communicating with the customer. These include, but are not limited to, APQP, PPAP, purchase orders, request for quote, 8-D reports, phone calls, email,

faxes, letters, and face-to-face meetings. These methods will be used to effectively communicate with our customers in relation to:

a. Product information;
b. Inquiries, contracts or order handling, including amendments;
c. Customer feedback, including customer complaints;
d. Handling or controlling customer property, and
e. Establishing specific requirements for contingency requirements, when relevant.

The Vice-President of Sales/Purchasing has the final responsibility for resolving differences between PML, INC. and the customer.

8.2.1.1 Customer Communication – Supplemental

PML, Inc. can communicate necessary information, including data, in a customer-specified language and format. Examples include, but are not limited to: computer-aided design data (Catia), electronic data exchange, email, internet, etc.

8.2.2 Determining Requirements for Products and Services

PML, Inc. is responsible for determining the following items related to the product:

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 PML, Inc.

This will be accomplished through effective communications with the customer.

8.2.2.1 Determining Requirements for Products and Services – Supplemental

These requirements shall include recycling, environmental impact, and characteristics identified as a result of the organization's knowledge of the product and manufacturing processes. These shall include but not be limited to the following:

a. All applicable government, safety, and environmental regulations related to acquisition, storage, handling, recycling, elimination, or disposal of material.

8.2.3 Review of the Requirements for Products and Services

8.2.3.1 General

PML, Inc. sales department initiates a feasibility study for proposed products prior to contracting to produce them. This review is documented using the ***Feasibility Review Form*** and is in accordance with the ***Customer Quote Review Level II Procedure.***

The review shall ensure that:

a. Product requirements are defined;
b. Contract or order requirements different from those previously expressed are resolved;
c. That PML, Inc. has the ability to meet the defined requirements, and
d. All Statutory or regulatory requirements applicable to the products and services.

The review will be recorded utilizing the feasibility form. This completed form, with all appropriate signatures, is kept in the part file. Where the customer provides no documented statement of requirement, the customer requirements are confirmed by the sales department prior to acceptance.

When product requirements are changed, PML, Inc. will ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements. PML, Inc. requires customer authorization to process a contract amendment. Sales/Customer Service is the customer liaison. They institute the amendment process, depending on the extent of the amendment, per the ***Order Review Level II Procedure.***

The Sales/Customer Service function maintains records of quotation and purchase order reviews for their respective departments per ***System Documentation Level II Procedure.***

8.2.3.1.1 Review of the Requirements for Products and Services – Supplemental

Waiver of the review mandated in 8.2.3.1 requires a documented customer authorization.

8.2.3.1.2 Customer-Designated Special Characteristics

Special characteristics are those characteristics identified on inspection standards, set-up manuals, etc. These characteristics have been identified by PML, Inc. to be the key characteristics in controlling product conformity. In the event a special characteristic is identified by the customer, PML, Inc. will conform to the requirements for designation, approval documentation and control as set forth by the customer. Special characteristics are identified during part feasibility analysis and APQP activities.

8.2.3.1.3 Organization Manufacturing Feasibility

PML, Inc. investigates, confirms and documents the manufacturing feasibility of the proposed products in the contract review process, including risk analysis. This is documented on the PML, Inc. feasibility review form, FSE-001.

The sales department manages the feasibility review form which requires input from manufacturing, quality assurance, engineering, sales, and material engineering to assess the feasibility of a part to fit within PML, Inc.'s production capabilities.

PML, Inc. will validate utilizing production runs, benchmarking studies or other appropriate methods to ensure its ability to make product to the required specifications and at the required rate.

8.2.3.2 Organization Manufacturing Feasibility – Supplemental

PML, Inc. shall retain documented evidence reflecting the results of the review and on any new requirements for products and services.

8.2.4 Changes to Requirements for Products and Services

When product requirements are changed, PML, Inc. will ensure relevant documents are amended and relevant personnel are made aware of the changed requirements. PML, Inc. requires customer authorization to process a contract amendment. Sales/Customer Service is the customer liaison. They will institute the amendment process, depending on the extent of the amendment, per the ***Order Review Level II Procedure.***

8.3 Design and Development of Products and Services

8.3.1 General

PML, Inc. shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services. PML, Inc. is not product design responsible, but is responsible for process design.

8.3.1.1 Design and Development of Products and Services – Supplemental

PML, Inc. does not design products. The material engineering group, supported by Marugo Rubber Industries, assists in the development of compounds to meet customer specifications. PML, Inc. will plan and control its processes to meet customer-designed product requirements. The APQP and PPAP processes are used to meet the standards required and emphasis shall be placed on error prevention. The design and development process is documented.
(***Refer Manufacturing Process Design Level II Procedure)***

8.3.2 Design and Development Planning

PML, Inc. uses a multidisciplinary approach to prepare for product realization. The APQP program consists of an internal cross-functional team that defines and documents how the quality requirements will be met and prepares the production of new or changed products. The APQP team uses appropriate techniques identified in the Advanced Product Quality Planning and PPAP reference manuals.

The activities include as appropriate:

a. Development/finalization and monitoring of special characteristics;
b. Development and review of FMEA's, including actions to reduce potential risks;
c. Development and review of control plans;
d. The nature, duration and complexity of the design and development activities;
e. The required process stages, including applicable design and development reviews;
f. The required design and development verification and validation activities;
g. The responsibilities and authorities involved in the design and development process;
h. The internal and external resource needs for the design and development of products and services;
i. The need to control interfaces between persons involved in the design and development process;
j. The need for involvement of customers and users in the design and development process;
k. The requirements for subsequent provision of products and services;
l. The level of control expected for the design and development process by customers and other relevant interested parties, and
m. The documented information needed to demonstrate the design and development requirements have been met.

8.3.2.1 Design and Development Planning – Supplemental

PML, Inc. shall plan APQP activities to include all interested parties, within the organization, and the supply chain, when applicable. PFMEA's, control plans, work instructions, etc. shall be created and reviewed during the design and development of manufacturing processes.

8.3.2.2 Product Design Skills

PML, Inc. is not responsible for product design, therefore there are no personnel with product design responsibility.

8.3.2.3 Development of Products with Embedded Software

PML, Inc. does not produce products or provide services with embedded software requirements.

8.3.3 Design and Development Inputs

Where appropriate, PML, Inc. will record:

a. Functional and performance requirements;
b. Applicable statutory and regulatory requirements;
c. Where applicable, information derived from previous similar designs and development activities;
d. Standard or codes of practice that PML, Inc. has committed to implement;
e. Potential consequences of failure due to the nature of the products and services;

f. All conflicting design and development inputs shall be resolved and documented, and
g. Other requirements essential for process design and development

8.3.3.1 Product Design Input

Not applicable to PML, Inc.

8.3.3.2 Manufacturing Process Design Input

PML, Inc. will identify, document and review the manufacturing process design input requirements, including:

a. Product design output data, including special characteristics;
b. Targets for productivity, process capability, timing and cost;
c. Alternative processes are not available in PML, Inc.;
d. Customer requirements, if any;
e. Experience from previous developments;
f. New materials;
g. Product material handling;
h. Safety points including, but limited to, PPE, ergonomics, etc.;
i. Design manufacturing and assembly, and
j. Error proofing appropriate for the potential risk and process requirements. (***Refer Manufacturing Process Design Level II Procedure)***

8.3.3 Special Characteristics

Special characteristics are those characteristics identified on inspection standards, set-up manuals, etc. These characteristics have been identified by PML, Inc., using multi-disciplinary teams and risk analysis, to be the key characteristics in controlling product conformity. In the event a special characteristic is identified by the customer, PML, Inc. will conform to the requirements for designation, approval documentation and control as set forth by the customer. A matrix is used to denote the customers' special characteristic symbol and the corresponding PML, Inc. symbol. Special characteristic key:

a. Regarding safety: SF
b. Regarding Regulation: RE
c. Special characteristics other than a and b: SC

8.3.4 Design and Development Controls

PML, Inc. shall apply controls to the design and development process, through the use of multi-disciplinary teams, APQP and PPAP, to ensure:

a. Process and product targets are defined;
b. Periodic reviews are conducted to evaluate the ability of the results development to meet requirements;
c. Activities are verified to ensure that the design and development outputs meet the input requirements;
d. Activities are verified to ensure that the design and development outputs meet the input requirements;
e. Validation is conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
f. Necessary actions are taken on problems determined during the reviews, or verification and validation activities, and
g. Documented information of these activities is retained in the customer PPAP packages and APQP records.

8.3.4.1 Monitoring

Measurements at specified stages of design and development are defined and analyzed during APQP activities. Summary results are discussed during management review meetings. When appropriate, these measurements may include quality risks, cost, lead times, critical paths and other measurements.

8.3.4.2 Design and Development Validation

Design and development validation will be performed in accordance with:

a. Customer requirements including program timing, and
b. Applicable governmental regulatory and industry standards.

8.3.4.3 Prototype Program

When required by the customer, PML, Inc. will have a prototype program and control plan. We will, whenever possible, use the same suppliers, tooling and manufacturing processes as will be used in production.

All performance-testing activities shall be monitored for timely completion and conformity to requirements. When services are outsourced, the organization shall include the type and extent of control in the scope of its quality management system to ensure that outsourced services conform to requirements.

8.3.4.4 Product Approval Process

PML, Inc. has a product approval process (PPAP) recognized by our customers. Product approval is subsequent to the verification of the manufacturing process. The product and manufacturing process approval procedure is also applied to suppliers, where appropriate.

PML, Inc. shall approve externally provided products and services, per ISO9001:2015 Section 8.4.3, prior to submission of part approval to customer. If required by the customer, PML, Inc. will obtain documented product approval prior to shipment. Records of such approval shall be required and properly retained.

8.3.5 Design and Development Outputs

The outputs of process design and development will be provided in a form that enables verification against the process design and development inputs and will be approved prior to release. These outputs will:

a. Meet the input requirements for process design and development;
b. Provide appropriate information for purchasing, production and for service provision;
c. Contain or reference product acceptance criteria;
d. Include monitoring and measurement requirements;
e. Specify the characteristics of the product that are essential for its safe and proper use, and
f. Retain documented information on design and development outputs.

8.3.5.1 Design and Development Outputs – Supplemental

PML, Inc. is not design responsible. This section is non-applicable.

8.3.5.2 Manufacturing Process Design Output

The manufacturing process design outputs will be expressed in terms that can be verified against manufacturing process design input requirements and validated. The manufacturing process design output shall include:

a. Specifications and drawings;
b. Special characteristics for product and manufacturing processes;
c. Identification of input variables that impact characteristics;
d. Tooling and equipment for production and control, including capability studies of equipment and processes;
e. Manufacturing process flow charts / layouts, including linkage of product, process and tooling;
f. Capacity analysis;
g. Process FMEA’s;
h. Maintenance plans and instructions;
i. Control plans;
j. Standard work and work instructions;
k. Process approval acceptance criteria;

l. Data for quality, reliability, maintainability, and measurability;
m. Results of error-proofing validation and identification activities, as appropriate, and
n. Methods of rapid detection, feedback and correction of product/manufacturing process nonconformities.

8.3.6 Design and Development Changes

Design and development changes shall be:

a. Identified and records maintained;
b. Reviewed, verified and validated;
c. Approved before implementation, if required, and
d. Evaluated for the effects of the changes on constituent parts and product already delivered, if required.

Records retained include:

a. Design and development changes;
b. Results of reviews;
c. Authorization of the changes, and
d. Actions taken to prevent adverse impacts.

(*Refer to Control of Changes Level II Procedures)*

8.3.6.1 Design and Development Changes – Supplemental

PML, Inc. has measures in place to control and react to changes impacting the product realization process. The effects of any change, including those changes caused by suppliers, are assessed, verified and validated. The activities shall be defined to ensure compliance with customer requirements. Changes are validated prior to implementation through the use of statistical techniques, where applicable.

For proprietary designs, impact on form, fit and function are reviewed with the customer so that all effects can be properly evaluated.

When required by the customer, additional verification/validation requirements, such as those required for new product introduction, will be performed. Any product realization change affecting customer requirements requires customer notification and approval. These requirements apply to product and manufacturing process changes. Customer approvals via the PPAP process are required.

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General

PML, Inc. shall ensure that externally provided processes, products and services conform to its and the customer requirements. PML, Inc. shall determine the controls to be applied to externally provided processes, products and services when:

a. Products and services from external providers are intended for incorporation into the organization's own products and services;
b. Products and services are provided directly to the customer(s) by external providers on behalf of the organization, and
c. A process, or part of a process, is provided by an external provider as a result of a decision by the organization.

The organization shall determine and apply the required criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

8.4.1.1 General - Supplemental

PML, Inc. shall include all products and services that affect customer requirements such as subassembly, sequencing, sorting, rework, and calibration services in the scope of their definition of externally provided products, processes, and services.

8.4.1.2 Supplier Selection Process

PML, Inc. has a documented supplier selection process. The process includes:

a. An assessment of the selected supplier's risk to product conformity and uninterrupted supply of the organization's product to their customers;
b. Quality performance;
c. Delivery performance;
d. An evaluation of the supplier's quality management system;
e. Multidisciplinary decision making; and
f. An assessment of software development capabilities, if applicable.

Other criteria, depending on supplier and or products provided, may include:

a. Volume of automotive business (absolute and as a percentage of total business);
b. Financial stability;
c. Purchased product, material, or service complexity;
d. Required technology (product or process);
e. Adequacy of available resources (e.g., people, infrastructure);
f. Design and development capabilities (including project management);
g. Manufacturing capability;
h. Change management process;
i. Business continuity planning (e.g., disaster preparedness, contingency planning);
j. Logistics process, and
k. Customer service.

(***Refer to Purchasing Level*** II ***Procedure***)

8.4.1.3 Customer-Directed Sources (Directed-Buy)

When required by the customer, PML, Inc. shall purchase products, materials, or services from customer-directed sources. All requirements of IATF16949:2016 Section 8.4, except for 8.4.1.2, are applicable to the control of customer-directed sources, unless specific agreements are otherwise contractually defined between PML, Inc. and the customer.

8.4.2 Type and Extent of Control

PML, Inc. shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.
PML, Inc. shall:

a. Ensure externally provided processes remain within the control of its quality management system, and
b. Define the controls that it intends to apply to an external provider and those it intends to apply to the resulting output.

Consideration will be given to:

a. The potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;
b. The effectiveness of the controls applied by the external provider, and
c. Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.2.1 Type and Extent of Control – Supplemental

PML, Inc. has a documented process to identify outsourced processes and to select the types and extent of controls used to verify conformity of externally provided products, processes, and services to internal and external customer requirements.

The process includes criteria and actions for escalation or reduction of the types and extent of controls and development activities based on supplier performance and assessment of product, material, or service risks.

8.4.2.2 Statutory or Regulatory Requirements

All materials used in the manufacturing of products will be reviewed by either purchasing or material engineering to ensure they satisfy current governmental and safety constraints on restricted, toxic and hazardous materials. This includes environmental, electrical and electromagnetic considerations applicable to the country of manufacture, the country of receipt, the country of shipment, and the customer-identified country of destination, if provided. If the customer defines special controls for certain products with statutory and regulatory requirements, the organization shall ensure they are implemented and maintained as defined, including at the

supplier's location. Purchasing is responsible for communication of requirements to suppliers via purchase orders.

8.4.2.3 Supplier Quality Management System Development

PML, Inc. requires suppliers of automotive products and services to develop, implement, and improve a quality management system certified to ISO9001:2015, unless otherwise authorized by the customer, with the ultimate objective of becoming certified to IATF16949:2016. Unless otherwise specified by the customer, the following sequence should be applied to achieve this requirement:

a. Compliance to ISO9001:2015 through second-party audits;
b. Certification to ISO9001:2015 through third-party audits; unless otherwise specified by the customer, suppliers to the organization shall demonstrate conformity to ISO9001:2015 by maintaining a third-party certification issued by a certification body bearing the accreditation mark of a recognized IAF MLA (International Accreditation Forum Multilateral Recognition Arrangement) member and where the accreditation body's main scope includes management system certification to ISO/IEC 17021;
c. Certification to ISO9001:2015 with compliance to other customer-defined QMS requirements (such as Minimum Automotive Quality Management System Requirements for Sub-Tier Suppliers [MAQMSR] or equivalent) through second-party audits;
d. Certification to ISO9001:2015 with compliance to IATF16949:2016 through second-party audits;
e. Certification to IATF16949:2016 through third-party audits (valid third-party certification of the supplier to IATF16949:2016 by an IATF-recognized certification body).

8.4.2.3.1 Automotive Product-Related Software or Automotive Products with Embedded Software

Not applicable.

8.4.2.4 Supplier Monitoring

Supplier performance will be monitored and documented. The following indicators will be monitored.

a. Delivered product quality;
b. Customer disruptions including field returns;
c. Delivery schedule performance (including incidents of premium freight);
d. Special status customer notifications related to quality or delivery issues, and
e. Dealer returns, warranty, field actions and recalls.

(Refer to the Purchasing Level II Procedure)

8.4.2.4.1 Second-Party Audits

PML, Inc. includes a second-party audit process in their supplier management approach. Second-party audits may be used for the following:

a. Supplier risk assessment;
b. Supplier monitoring;
c. Supplier QMS development;
d. Product audits, and
e. Process audits.

Based on risk analysis, including product safety/regulatory requirements, performance of the supplier, and QMS certification level, at a minimum, the organization shall document the criteria for determining the need, type, frequency, and scope of second-party audits.

Records and reports of second-party audits are retained. If the scope of the second-party audit is to assess the supplier's quality management system, then the approach shall be consistent with the automotive process approach.

8.4.2.5 Supplier Development

The organization shall determine the priority, type, extent, and timing of required supplier development actions for its active suppliers.

Determination inputs shall include but are not limited to the following:

a. Performance issues identified through supplier monitoring. (Section 8.4.2.4);
b. Second-party audit findings (Section 8.4.2.4.1);
c. Third-party quality management system certification status, and
d. Risk analysis.

Actions necessary to resolve open (unsatisfactory) performance issues will be implemented and PML, Inc. will pursue opportunities for continual improvement.

8.4.3 Information for External Providers

PML, Inc. shall ensure the adequacy of requirements prior to their communication to the external provider.

Requirements for the following will be supplied to the provider:

a. The processes, products and services to be provided;
b. The approval of products and services, methods, processes and equipment and the release of products and services;
c. Competence, including any required qualification of persons;
d. The external providers' interactions with the organization;
e. Control and monitoring of the external providers' performance to be applied by the organization, and
f. Verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

8.4.3.1 Information for External Providers – Supplemental

PML, Inc.'s Purchasing department communicates all applicable statutory and regulatory requirements and special product and process characteristics to their suppliers and requires the suppliers to cascade all applicable requirements down the supply chain to the point of manufacture.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

PML, Inc. will plan and carry out production and service provision under controlled conditions. Controlled conditions include, as applicable:

a. The availability of information that describes the characteristics of the product and the results achieved;
b. The availability of work instructions, as necessary;
c. The use of suitable equipment;
d. The use of suitable infrastructure and environment for the operation of processes;
e. The appointment of competent persons, including any required qualifications;
f. The availability and use of monitoring and measuring devices;
g. The validation, and periodic re-evaluation, of the ability to achieve planned results of the processes for production and service prevision, where the resulting output cannot be verified by subsequent, monitoring and measurement;
h. Human error-proofing;
i. The implementation of monitoring and measurement, and
j. The implementation of release, delivery and post-delivery activities.

8.5.1.1 Control Plan

PML, Inc. develops control plans at all levels appropriate for the product supplied. PML shall have a control plan for pre-launch and production that shows linkage and incorporates information form the design risk analysis (if provided by the customer), process flow diagram, and manufacturing process risk analysis outputs (such as FMEA). The control plans are developed using a multi-disciplinary approach. The control plans will include:

a. The controls used for the manufacturing process control;
b. First-off/last-off part validation;
c. Methods for monitoring of control exercised over special characteristics defined by both the customer and the organization;
d. Customer-required information, if any, and
e. The specified reaction plan when the process becomes unstable or not statistically capable.

The quality department is responsible for ensuring that control plans are reviewed and updated at a set frequency based on risk analysis or when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, customer complaints, after corrective actions, or FMEA's. If required by the customer, PML will obtain customer approval after review or revision of the control plan.

8.5.1.2 Standardize Work-Operator Instructions and Visual Standards

PML, Inc. shall ensure that standardized work instructions are:

a. Communicated and understood by the associates who are responsible for performing the work;
b. Legible;
c. Include rules for operator safety;
d. Presented in the language(s) understood by the personnel responsible to follow them, and
e. Accessible for use at the designated work area(s).

8.5.1.3 Verification of Job Set-Ups

PML, Inc. shall:

a. Verify job set-ups when performed, such as an initial run of a job, material changeover, or job change that requires a new set-up;
b. Maintain documented information for set-up personnel;
c. Use statistical methods of verification, where applicable;
d. Perform first-off/last-off part validation, as applicable, first-off parts should be retained for comparison with the last-off parts. Where appropriate, last-off-parts should be retained for comparison with first-off parts in subsequent runs, and
e. Retain records of process and product approval following set-up and first-off/last-off part validations.

8.5.1.4 Verification after Shutdown

PML, Inc. shall define and implement the necessary actions to ensure product compliance with requirements after planned or unplanned production shutdown period.

8.5.1.5 Total Productive Maintenance

PML, Inc. shall develop, implement, and maintain a documented total productive maintenance system.

At a minimum, the system shall include the following:

a. Identification of process equipment necessary to produce conforming product at the required volume;
b. Availability of replacement parts for the equipment identified in item a);
c. Provision of resource for machine, equipment, and facility maintenance;
d. Packaging and preservation of equipment, tooling, and gauging;

e. Applicable customer-specific requirements;
f. Documented maintenance objectives
g. Regular review of maintenance plan and objectives and a documented action plan to address corrective actions where objectives are not achieved;
h. Use of preventive maintenance methods;
i. Use of predictive maintenance methods, as applicable, and
j. Periodic overhaul.

(***Refer to Maintenance Management Level II Procedure)***

8.5.1.6 Management of Production Tooling and Manufacturing, Test, Inspection Tooling and Equipment

PML, Inc. shall provide resources for tool and gauge design, fabrication, and verification activities for production and service materials and for bulk materials, as applicable.

PML, Inc. shall establish and implement a system for production tooling management, whether owned by the organization or the customer, including:

a. Maintenance and repair facilities and personnel;
b. Storage and recovery;
c. Set-up;
d. Tool-change programs for perishable tools;
e. Tool design modification documentation, including engineering change level of the product;
f. Tool modification and revision to documentation;
g. Tool identification, such as serial or asset number;
h. The status, such as production, repair or disposal;
i. Ownership, and
j. Location.

PML, Inc. shall verify that customer-owned tools, manufacturing equipment, and test/inspection equipment are permanently marked in a visible location so that the ownership and application of each item can be determined.

PML, Inc. shall implement a system to monitor these activities if any work is outsourced.

(Refer to Tooling Management Level II Procedure)

8.5.1.7 Production Scheduling

Production is scheduled in order to meet customer requirements, such as Just-In-Time (JIT) and is supported by an AS400 information system that permits access to production information at key stages of the process and is order driven. PML, Inc. shall include relevant planning information during production scheduling, e.g., customer orders, supplier-on-time delivery performance, capacity, shared loading (multi-part station), lead time, inventory level, preventative maintenance, and calibration.

8.5.2 Identification and Traceability

PML, Inc. identifies the product by suitable means throughout the product realization process. The traceability program maintains identification of raw material from receipt, during all stages of production, through to our customers. ***Product Identification and Traceability Level II Procedure*** defines the traceability program activities.

PML, Inc. applies specific identification on the product or product container as required by the customer and shall retain documented information necessary to ensure traceability.

8.5.2.1 Identification and Traceability – Supplemental

PML, Inc. shall conduct an analysis on internal, customer and regulatory traceability requirements for all automotive products, including developing and documenting traceability plans, based on the levels of risk or failure severity for employees, customers, and consumers. These plans shall define the appropriate traceability systems, processes, and methods by product, process, and manufacturing location that:

a. Enable the organization to identify nonconforming and/or suspect product;
b. Enable the organization to segregate nonconforming and/or suspect product;
c. Ensure the ability to meet the customer and/or regulatory response time requirements;
d. Ensure documented information is retained in the format (electronic, hardcopy, archive) that enables the organization to meet the response time requirements;
e. Ensure serialized identification of individual products, if specified by the customer or regulatory standards, and
f. Ensure the identification and traceability requirements are extended to externally provided products with safety/regulatory characteristics.

8.5.3 Property belonging to Customers or External

Providers

PML, Inc. verifies customer supplied material, tooling and packaging meet agreed upon specifications. Safe storage and maintenance are provided for items supplied by the customer.

Any product that is lost, damaged or is otherwise unsuitable for use is recorded and reported to the customer and other required interested parties. The customer has the responsibility to provide PML, Inc. acceptable product that meets agreed upon specifications.

8.5.4 Preservation

PML, Inc. shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

8.5.4.1 Preservation – Supplemental

Preservation shall include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection. Preservation shall apply to materials and components from external and/or internal providers from receipt through processing, including shipment and until delivery to/acceptance by the customer.

To detect deterioration, the organization shall assess at appropriate planned intervals the condition of product in stock, the place/type of storage container, and the storage environment. The organization shall use the FIFO inventory management system to optimize inventory turns over time and ensure stock rotation.

Obsolete product is controlled in the same manner as that of nonconforming product.

Customer requirements for preservation, packaging, shipping, and labeling requirements shall be complied with.

8.5.5 Post-Delivery Activities

PML, Inc. will meet requirements for post-delivery activities associated with the products and services. We will determine the extent of post-delivery activities that are required and shall consider the following:

a. Statutory and regulatory requirements;
b. Potential undesired consequences associated with our products and services;
c. The nature, use and intended lifetime of our products and services;
d. Customer requirements, and

e. Customer feedback.

Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposition.

8.5.5.1 Feedback of Information from Service

PML, Inc. shall ensure that a process for communication of information on service concerns to manufacturing, material handling, logistics, engineering, and design activities is established, implemented, and maintained.

PML, Inc. will be aware of non-conforming products and materials that may be identified at the customer or in the field.

"Service concerns" shall include the results of field failure test analysis.

8.5.5.2 Service Agreement with Customer

Not applicable to PML, Inc.

8.5.6 Control of Changes

PML, Inc. shall review and control changes for production or service provision, to ensure continuing conformity with requirements. It will retain documented information describing the results of the review of changes, the person authorizing the change, and any necessary actions arising from the review.

8.5.6.1 Control of Changes – Supplemental

PML, Inc. shall have a documented process to control and react to changes that impact product realization. The effect of all changes will be accessed by the following:

a. Define verification and validation activities to ensure compliance with customer requirements;
b. Validated changes before implementation;
c. Document evidence of related risk analysis, and
d. Retain records of verification and validation.

All changes made will require a production trial run for verification of changes to validate the impact of these changes on the manufacturing process. If required by the customer, PML, Inc. will:

a. Notify the customer of any planned customer changes after the most recent product approval;
b. Obtain documented approval prior to implementation of the change, and
c. Complete additional verification or identification requirements, such as production trial run and new production validation.

8.5.6.1.1 Temporary Change of Process Controls

If required, PML, Inc. will identify, document, and maintain a list of the process controls, including inspection, measuring, tests, and error-proofing devices, that includes the primary process control and the approved back-up or alternative methods. PML, Inc. will document the process that manages the use of alternative use methods. We will include in this process, based on risk-analysis, severity and the internal approvals to be obtained prior to production implementation of the alternate control method.

If required, we will obtain approval from our customer prior to shipping the product.

Work instructions shall be available for each alternative process control method. PML, Inc. will review the operation of alternate process controls on a daily basis to verify standard work with a goal to return to the standard process as defined by the control plan as soon as possible.

PML, Inc. shall implement traceability of all product produced with any alternate process control devices or processes.

Restart verification is documented for a defined period based on severity and confirmation that all features of the error-proofing device or process are effectively reinstated. The 1st piece / last piece procedure will be followed.

8.6 Release of Products and Services

PML, Inc. shall implement planned arrangements, at appropriate stages to verify that the product and service requirements have been met. PML, Inc. shall retain documented information on the release of products and services. The information shall include:

a. Evidence of conformity, and
b. Traceability to the person who authorized the release.

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

8.6.1 Release of Products and Services – Supplemental

PML, Inc. has measures in place to control and react to changes impacting product realization. The change effects, including those changes caused by suppliers, are assessed, verified and validated. Activities shall be defined to ensure compliance with customer requirements. Changes are validated prior to implementation. This will be done through statistical techniques, where applicable.

For proprietary designs, impact on form, fit and function will be reviewed with the customer so that all effects can be properly evaluated. When required by the customer, additional

verification/identification requirements, such as those required for new product introduction, are met. Any product realization change affecting customer requirements requires customer notification and approval.

8.6.2 Layout Inspection and Functional Testing

A layout inspection and functional verification to applicable customer engineering, material and performance standards will be performed for each product as specified in the control plans. Results will be available for customer review.

- *Layout inspection is a complete measurement of all product dimensions shown on the design record.*
- *The frequency of layout inspection is determined by the customer.*

8.6.3 Appearance Items

"Appearance Items" are not designated by the customers at this time. If appearance items are designated by the customer PML, Inc. will do the following:

a. Provide appropriate resources including lighting for evaluation;
b. Provide masters for color, grain, gloss, metallic brilliance, texture, distinctness of image, and haptic technology as appropriate;
c. Maintenance and control of appearance masters and evaluation equipment, and
d. Verification that associates are trained to make appearance evaluations in a competent manner.

8.6.4 Verification and Acceptance of Conformity of Externally Provided Products and Services

PML, Inc.'s incoming quality system uses one or more of the following methods, as specified on the receiving inspection instructions, to assure conformance of externally provided products and services:

a. Receipt of statistical data and evaluation;
b. Receiving inspection or testing (sampling based on performance);
c. Second or third-party assessments or audits of the subcontractor locations;
d. Evaluations by accredited contractors or test laboratory, and
e. Another method agreed with the customer.

The controlling procedures for receiving inspection and test *are* ***Incoming Material Control/Accelerated, Incoming Material Control/Master Batches, and Receiving Inspection of Non- Rubber Materials Level II Procedures.***

8.6.5 Statutory and Regulatory Conformity

Prior to release of externally provided products into its production flow, the organization shall confirm and be able to provide evidence that externally provided processes, products, and services conform to the latest applicable statutory, regulatory, and other requirements in the countries where they are manufactured and the customer-identified countries of destination, if provided.

8.6.6 Acceptance Criteria

PML, Inc. has defined acceptance criteria and, where required, the customer has approved them. For attribute data sampling, the acceptance level is zero defects. (refer to 9.1.1.1)

8.7 Control of Non-Conforming Outputs

8.7.1 General

PML, Inc. will ensure outputs not conforming to requirements are identified and controlled to prevent their unintended use or delivery. It will deal with non-conforming outputs in one or more of the following ways:

a. Correction
b. Segregation, containment, return or suspension of provision of products and services;
c. Informing the customer, and or
d. Obtaining authorization for acceptance under concession.

Conformity to the requirements shall be verified when non-conforming outputs are corrected.

8.7.1.1 Customer Authorization for Concession

PML, Inc. will obtain a customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved.

PML, shall obtain customer authorization prior to further processing for “use as is” and rework dispositions of non-conforming products. If sub-components are re-used in the manufacturing process, it will be clearly communicated to the customer in the concession of deviation permit.

PML, Inc. will maintain a record of the expiration date or quantity authorized. It will ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped on an authorization will be properly identified on each shipping container.

This applies equally to purchased product. PML, Inc. will agree with any requests from suppliers before submission to the customer.

8.7.1.2 Control of Nonconforming Product – Customer-Specified Process

PML, Inc. shall comply with applicable customer-specified controls for nonconforming products.

8.7.1.3 Control of Suspect Product

PML, Inc. shall ensure that all product with unidentified or suspect status is controlled as nonconforming product. It will ensure all associates receive training for containment of suspect and nonconforming product.

8.7.1.4 Control of Rework Product

Product may be reprocessed per standard process procedures and work instructions. Rework instructions are utilized by the appropriate personnel and are accessible at their workstations. Reference the ***Rework, Sort, Reject Level II Procedure.***

Repaired or reworked product is re-inspected according to the inspection or laboratory instructions and/or control plan.

PML, Inc. shall utilize risk analysis such as FMEA to assess risks in the rework process prior to reworking the product. Customer approval will be obtained, if required, prior to reworking products. PML, Inc. will retain documented information on the disposition of reworked product including quantity, disposition, disposition date, and applicable traceability information.

8.7.1.5 Control of Repaired Product

Currently PML, Inc. does not repair product. If in the future we must repair product, we will:

a. Assess risks in the repair process;
b. Obtain approval from the customer before beginning the repair make a documented process for repair in accordance to the control plan or other documented information;
c. Make work instructions for disassembly or repair, including re-inspection and traceability requirements;
d. Obtain a documented customer authorization for concession for the product to be repaired, and
e. Retain documented information on the disposition of repaired product including quantity, disposition, disposition date, and applicable traceability information.

8.7.1.6 Customer Notification

PML, Inc. shall immediately notify the customer in the event that non-conforming product has been shipped. Initial communication will be followed with detailed documentation of the event.

8.7.1.7 Nonconforming Product Disposition

PML, Inc. shall have a documented process for disposition of nonconforming product that is not subject to rework. PML, Inc. will not divert nonconforming product to service or other use without prior customer approval. All nonconforming product is placed in a red reject bucket. The red reject buckets are emptied into the trash containers and the trash containers are emptied in to the trash trailer. When full, this trailer is taken to the landfill for disposal by means of incineration or burial.

8.7.2 General

PML, Inc. will retain documented information that:

a. Describes the nonconformity;
b. Describes the actions taken;
c. Describes any concessions obtained, and
d. Identifies the authority deciding the action is respect of the nonconformity.

PML, Inc.
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Section IX – Performance Evaluation

9.0 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

PML, Inc. plans and implements the monitoring, measurement, analysis and improvement processes needed:

a. To demonstrate conformity to product requirements;
b. To ensure conformity of the quality management system;
c. To continually improve the effectiveness of the quality management system.
d. To verify that the process flow diagram PFEMA and control plan are implemented, and
e. To ensure adherence to measurement techniques, sampling plans, acceptance criteria, proper measurement data records, and reaction plans and the escalation process, when criteria are not met.

PML, Inc. controls the application of statistical techniques and the implementation of corrective action indicated by the techniques. Proper documentation shall be retained.

9.1.1.1 Monitoring and Measurement of Manufacturing Processes

PML, Inc. shall perform process studies on all new manufacturing processes to verify process capability and to provide additional input for process control, including those for special characteristics.

PML, Inc. will maintain manufacturing process capability or performance results as specified by the customer's part approval process requirements. The organization shall verify that the process flow diagram, PFMEA, and control plan are implemented, including adherence to the following:

a. Measurement techniques;
b. Sampling plans;
c. Acceptance criteria;
d. Records of actual measurement values and/or test results for variable data;
e. Reaction plans and escalation process when acceptance criteria are not met.

Significant process events, such as tool change or machine repair, shall be recorded and retained as documented information.
PML, Inc. shall initiate a reaction plan indicated on the control plan and evaluated for impact on compliance to specifications for characteristics that are either not statistically capable or are unstable. 100% inspection will be required when processes are not stable.

A corrective action plan shall be developed and implemented by the organization indicating specific actions, timing, and assigned responsibilities to ensure that the process becomes stable and statistically capable. The plans are reviewed with and approved by the customer, when required. The organization shall maintain records of effective dates of process changes.

9.1.1.2 Identification of Statistical Tools

Appropriate statistical tools for each process are determined during the APQP process and included in the control plan and PFMEA, when applicable.

9.1.1.3 Application of Statistical Concepts

Basic statistical concepts, such as variation, control (stability), process capability and over-adjustment are understood and utilized throughout the organization.

9.1.2 Customer Satisfaction

PML, Inc. receives reports from many customers showing our performance on areas such as quality rating, cost, and delivery. Additionally, our sales department measures customer satisfaction and perception by noting the level of satisfaction the customer communicated during the sales visit on their sales report. This report is copied to various departments within PML to ensure the customer's views are understood.

9.1.2.1 Customer Satisfaction – Supplemental

Customer satisfaction is monitored by continual performance evaluation of the product realization process. Performance indicators are based on objective data and include, but are not limited to:

a. Delivered part quality performance;
b. Customer disruptions including field returns;
c. Field returns, recalls, and warranty data;
d. Delivery schedule performance (including incidents of premium freight), and
e. Customer notifications related to quality or delivery issues.

PML, Inc. monitors the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and efficiency of the process.

9.1.3 Analysis and Evaluation

PML, Inc. will determine, collect and analyze appropriate data demonstrating the suitability and effectiveness of the quality management system and evaluate where continual improvement of the effectiveness of the quality management system can be made. This will include data generated by monitoring and measurement from other relevant sources.

The analysis of data shall provide information relating to:

a. Customer satisfaction;
b. Evaluate the performance and effectiveness of the quality management system;
c. To determine if planning has been implemented effectively;
d. To determine the effectiveness of actions taken to reduce risks and opportunities;
e. To determine the need for improvements to the quality management system;
f. Conformity to product requirements;
g. Characteristics and trends of processes and products including opportunities for preventive action, and
h. Supplier performance.
(***Refer to Continuous Improvement Level II Procedure***)

9.1.3.1 Prioritization

Trends in quality and operational performance will be compared with progress toward objectives and lead to action to support the following:

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

When available, data will be compared with those of competitors and/or an appropriate benchmark.

9.2 Internal Audit

9.2.1 & 9.2.2 General Requirements

Internal quality audits verify whether quality activities comply with planned arrangements and determine the effectiveness of the quality system. PML, Inc. maintains documented procedures for planning and implementing internal quality audits. Reference the procedure, ***Quality System Audit/Environmental System Audi Level II Procedure.***

Internal audits are performed by team members who do not have direct responsibility for the area being audited. Audits are scheduled based on status, importance of the activity and to comply with the required frequencies mandated.

Audit teams record and present audit results to personnel responsible for the area audited. Management personnel for the audited area are required to determine the root cause, take timely corrective action, and verify the implementation and effectiveness of actions taken on any deficiencies found during the audit. Records are maintained from each audit. Auditors verify and record the implementation and effectiveness of the corrective actions taken.

9.2.2.1 Internal Audit Program

Internal auditing covers all shifts, processes and activities and is conducted according to an audit schedule updated annually. When internal/external non-conformances, customer complaints, process changes and other risks are identified, the priorities of the program will be adjusted.

Auditors will preserve adequate evidence to justify decisions concerning whether the process audited is effective and efficient. Evidence will include, where applicable, control plans, PFMEA's, documents, quality objectives and performance to the quality objectives, specific customer requirements, etc.

The effectiveness and efficiency of the internal audit program will be reviewed in Management Review.

9.2.2.2 Quality Management System Audit

PML, Inc. will audit its quality management system to verify compliance with the IATF16949:2016 and any additional quality management system requirements, including customer specific requirements. All management system processes will be audited, no less than, once every 3 years. When required, customer specific audit approaches will be used. will be reflected in the program.

9.2.2.3 Manufacturing Process Audit

PML, Inc. will audit each manufacturing process to determine its effectiveness and efficiency. When required, PML, Inc. will use customer specific approaches for these audits. Each shift will be audited where the process occurs, including shift change. Specific items to be audited include, but are not limited to training, cleanliness and orderliness, documents, measurement systems, PFMEA's, control plans, and calibrations. Each process will be audited, at a minimum, once per 3 years. Control plans and PFMEA's will be retained as evidence and a decision documented as to whether they were or were not effectively implemented in the process.

9.2.2.4 Product Audit

PML, Inc. conducts audits of packaged final product to verify conformance to customer specified requirements at an appropriate frequency. Depending on customer required PPM performance,

frequency of product audits may be adjusted. When required customer specific audit approaches will be used.

9.3 Management Review

9.3.1 General

Management review meetings are conducted at defined intervals to determine adequacy, effectiveness and continuing suitability of the quality system to satisfy the requirements of IATF16949:2016, customer requirements and PML, Inc.'s stated quality policy and objectives. This review includes the need for changes to the quality management system, including the quality policy and quality objectives.

9.3.1.1 Management Review – Supplemental

This review includes all requirements of the quality management system and its performance trends as an essential part of the continual improvement process. Management reviews will be held at a minimum, annually. When the performance of the QMS dictates reviews will be increased.

Part of the management review will be the monitoring of the quality objectives, and the regular reporting and evaluation of the cost of poor-quality. These results are recorded to provide, aT a minimum, evidence of the achievement of:

a. The quality objectives specified in the business plan, and
b. Customer satisfaction with product supplied

9.3.2 Management Review Inputs

The input to management reviews will include information on:

a. Results of audits;
b. Customer feedback and satisfaction;
c. Process performance and product conformity;
d. Status of non-conformities and preventive and corrective actions;
e. Follow-up actions from previous management reviews;
f. Changes, whether internal or external, that could affect the quality management system;
g. Recommendations for improvement;
h. The extent to which quality objectives have been met;
i. The performance of external providers;
j. The adequacy of resources;
k. Monitoring and measuring results;
l. The effectiveness of actions taken to address risks and opportunities, and
m. Opportunities for improvement

9.3.2.1 Management Review Inputs - Supplemental

Additional inputs are as follows:

a. Cost of poor-quality;
b. Measures of process effectiveness;
c. Measures of process efficiency;
d. Product conformance;
e. Assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new products;
f. Customer satisfaction;
g. Review of performance against maintenance objectives;
h. Warranty performance;
i. Review of customer scorecards;
j. Identification of potential field failures identified through risk analysis, and
k. Actual field failures and their impact on safety or the environment

9.3.3 Management Review Outputs

The output from the management review will be documented and include any decisions and actions related to:

a. Improvement of the effectiveness of the quality management system and its processes;
b. Changes required for the QMS;
c. Improvement of product related to customer requirements, and
d. Required resources.

9.3.3.1 Management Review Outputs – Supplemental

Action plans shall be developed and documented when customer performance targets are not met.

(***Refer Management Review Level II Procedure)***

Section X - Improvement

10.0 Improvement

10.1 General

PML, Inc. shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. Consideration shall be given to:

a. Associate safety;
b. Defect reduction;
c. Productivity increases;
d. VE/VA activities;
e. New technologies;
f. Corrective actions;
g. Preventive actions,
h. Other improvement activities.

PML, Inc. associates are encouraged to contribute ideas for continual improvement through the suggestion box located in the manufacturing facility. Additionally, associates may be members of kaizen teams offering continuous improvement ideas.

10.2 Nonconformity and Corrective Action

10.2.1 & 10.2.2 - General Information

Documented procedures prevent the unintentional use or shipment of product that does not conform to specified requirements. Questionable product is identified and segregated, when practical, in the nonconforming area. Product is evaluated, disposition made, and the findings documented. Findings are presented to involved functions and management for assessment. Reference ***Nonconforming Material Control Level II Procedure.***

Documented procedures ensure that suspect as well as nonconforming material or product is not unintentionally used or shipped. If suspect and or non-conforming product is shipped to the customer, the customer will be informed, and a determination will be made of the actual impact to the customer and actions taken to address the consequences.

Nonconforming or suspect material or product and any quarantine areas are visually identified.

The Quality Manager is assigned the responsibilities for controlling nonconforming product. Documented procedures define the inspection, testing and handling of suspect and nonconforming material and product.
PML, Inc. dispositions material or product as:
a. Accepted, meets specified requirements;
b. Reprocessed, to meet the specified requirements;
c. Re-graded for alternate application, if the alternate application specified is met;
d. Repaired with concession, customer authorization is required;
e. Rejected or scrapped.

The need for action will be evaluated to eliminate causes of the non-conformances in order to prevent further occurrence. Actions will include:
a. Reviewing nonconformities (including customer complaints);
b. Determining the causes of nonconformities;
c. Determining whether similar non-conformances exist or could potentially occur;
d. Determining and implementing action needed;
e. Records of the results of action taken;
f. Reviewing corrective action taken;
g. Update risks and opportunities determined during planning, if required, and
h. Make required changes to the QMS, if required.

Corrective actions will be appropriate to the effects of the non-conformities encountered.

PML, Inc. effects action to eliminate the cause of nonconformities to prevent recurrence. Actions and results will be documented. (***refer to Corrective Action Level II Procedure)***

10.2.3 Problem Solving

PML, Inc. has a documented process for problem solving that includes:
a. Defined approaches for various types and scales of problems (e.g., new product development, current manufacturing issues, field failures, audit findings);
b. Containment, interim actions, and related activities necessary for control of nonconforming outputs (see Section 8.7);
c. Root cause analysis, methodology used, analysis, and results;
d. Implementation of systemic corrective actions, including consideration of the impact on similar processes and products;
e. Verification of the effectiveness of implemented corrective actions;
f. Reviewing and, where necessary, updating the appropriate documented information (e.g., PFMEA. control plan).

When required, PML, Inc. shall use customer specified techniques.

10.2.4 Error Proofing

PML, Inc. has a documented process to determine the use of appropriate error-proofing methodologies. Details of the method used shall be documented in the process risk analysis (such as PFMEA) and test frequencies are documented in the control plan.

Challenge parts are used, where applicable, to test the function of the devices. Records of pass or fail are maintained. Where possible, challenge parts, are identified, controlled, verified, and calibrated. Reaction plans are in place in the event error-proofing devices are found to functioning improperly.
(***Refer to Manufacturing Process Design Level II Procedure***)

10.2.5 Warranty Management System

When PML, Inc. is required to provide warranty for their products, it shall implement a warranty management process. There will be included a method for warranty part analysis, including NTF (no trouble found). When specified by the customer, PML, Inc. will implement the required warranty management process.

10.2.6 Customer Complaints / Field Failure Test Analysis

PML, Inc. effectively analyzes product returned by the customer. Where appropriate, corrective actions are initiated, and processes are changed to prevent recurrence. Findings from the analysis, corrective actions and follow-up findings are recorded. The data is maintained and is made available upon request.

10.3 Continuous Improvement

PML, Inc. will continually improve the effectiveness of the quality management system using the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

10.3.1 Continual Improvement – Supplemental

PML, Inc has a documented process for continual improvement. The process includes:

a. Identification of the methodology used, objectives, measurement, effectiveness, and documented information;
b. A manufacturing process improvement action plan with emphasis on the reduction of process variation and waste; and
c. Risk analysis (such as FMEA).

NOTE Continual improvement is implemented once manufacturing processes are statistically capable and stable or when product characteristics are predictable and meet customer requirements.

(***Refer to Continuous Improvement Level II Procedure***)

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Level II Procedures:

HR.18.01 Training
ME.10.01 Incoming Material Control / Accelerated
ME.10.02 Incoming Material Control / Masterbatch
ME.10.06 Receiving Inspection of Non-Rubber Materials
ME.10.07 Laboratory Requirements
ME.10.08 IMDS Procedure
MG.01.02 Management Review
MG.02.01 Continuous Improvement
MT.09.02 Maintenance Management
PE.02.03 Tooling Management
PE.03.01 Control of Changes
PE.04.01 Manufacturing Process Design
PR.06.06 Purchasing Procedure
QC.05.05 System Documentation
QC.05.09 Drawing and Standard Control
QC.08.01 Product Identification and Traceability
QC.11.01 Calibration System
QC.13.01 Non-Conforming Material Control
QC.13.02 Rework, Sort, Reject Procedure
QC.14.01 Corrective Action
QC.14.02 Preventive Action
QC.17.01 Quality System Audit / Environmental System Audit
QC.21.01 Product Safety Management
QC.22.01 Internal and Second Party Auditor Competency
QC.23.01 Customer Supplier Manual Control
SL.03.01 Customer Quote Review
SL.03.02 Order Review Procedure

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