Prime Machine

Quality Systems Manual

Revision	Reason for change	Rev. Date	Approval
AA	See Rev Change Table	5/12/2023	KBB

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Introduction

Prime Machine Inc. (PMI) has implemented a quality management system (QMS) to document and continually improve the company's business practices, better understand, and satisfy the requirements and expectations of its customers and to improve the overall performance of the company.

PMI's QMS complies with the intent of International Standard SAE AS9100D. This system addresses the development, production, and servicing of the company's products and services.

The manual is divided into sections that correlate to the QMS sections of SAE AS9100D.

This manual describes the QMS and the responsibilities, authorities, and interrelationship between PMI personnel. The manual also provides procedures and references for activities ensuring compliance with the requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the SAE AS9100D Standard and the company's best business practices. These practices are dynamic and are maintained to ensure customer satisfaction and continuous improvement.

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

Quality Manual Distribution Policy

PMI's QMS documentation, quality manual, procedures, process flows, and quality forms are on-line documents. The most current revision of each document is the on-line version. All paper copies of the QMS documents are "reference only" and their current revision level shall be verified before use. Training on how to access the QMS documentation will be provided to all employees as part of their employee orientation.

Access to this manual is provided to the customer and/or regulatory agencies upon request or where appropriate to satisfy contractual obligation or compliance with our customer's internal quality systems.

Section 1: Scope

1.1 General

PMI is a multi-faceted service and production organization with a wide range of customers. This quality manual outlines the policies, procedures, and requirements of the PMI QMS. The system is structured to meet the intent of the conditions set forth in the international standard AS9100D.

Section 2: Normative References

2.0 Quality Management System References

The following document was used as reference during the preparation of the QMS:

- SAE International Aerospace Standard AS9100:D

Section 3: Terms and Definitions

3.0 Quality Management System Definitions

- **Contract Review / Proposal –** The response to a customer's work scope requests. This is where the intent to meet specific customer requirements is initiated and documented.
- **Customer Owned Property** - Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.
- **Customer Supplied Product** - Any type of service or material supplied to be utilized in the manufacture, modification, or repair of customer-owned property.
- **Job Folder-** The job folder is the final collection point for all paperwork associated with a specific job that serves as the historical documentation for the work performed. All pertinent documents will be contained in the folder, e.g., drawings, work orders, material certifications, inspection sheets, etc. The job folder is considered the historical record of note for each job.
- **Material Review-** Material review is the activity performed by the material review board (MRB) to determine the disposition of products that do not meet specification. This activity is performed by the project manager, shop management, and quality personnel and may rework, repair, scrap or use as is any component under their review. **(**See PMP-007).

- **Network Job Folder –** This refers to the directory created on the PMI computer network for each job. All data in the physical job folder shall be scanned into this folder for easier access to all and for simple storage.
- **PMF**-PMI flow diagrams or forms. These are also considered support documentation for this manual.
- **PMP**- PMI procedure. These are also considered support documentation for this manual.
- **PPC**-PMI process control procedure. These are standard procedures that PMI had developed for recurring and/or specialized work. These PPC's are referenced in the work orders as required for additional process control.
- **Product** – The end item result of meeting all contract terms and conditions (manufactured goods, merchandise, services etc.)
- **QFM** - PMI quality control form
- **Quality Records** – Documentation of those activities where records must be maintained – this will be specified in the procedure or work instruction documents, as applicable.
- **Source Inspection**- An agreement made with the customer, government, or their designee, to verify conformance of a product at PMI or at PMI external provider's premises.
- **Work Order Packet-** The work order packet is the printed document package that defines the sequence of operations to be performed in the execution of a specific work order, including inspection points. This package contains the appropriate inspection forms, drawings, work order, and other data gathered as the job progresses towards completion. This document package is enclosed in a clear envelope which contains pertinent in-process documentation that travels with the parts on the shop floor.
- **WIP** – "Work in process" status for the operations performed on a project.
- **Work Order -** This is a computer-generated sequence of operations that defines the complete scope of work to be performed for a specific job. The electronic version of the work order is considered the sole authority data for work in process, and it is maintained within Global Shop Solutions (GSS) with the most current sequence of operations. The work order is the initial planning step in the execution of a job, and as changes are made to work in process the work order shall be updated. (See PMP-003)

3.1 Counterfeit Part

An unauthorized copy, imitation, substitute, or modified part (material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer. May include false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics.

3.2 Critical Items

Those items (functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product; including safety, performance, form, fit, function, manufacturability, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

3.3 Key Characteristic

An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life or manufacturability that requires specific actions for controlling variation.

3.4 Product Safety

The state in which a product can perform to the designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

3.5 Special Requirements

If requirements identified by the customer or determined by PMI have high risks of being achieved, they are included in the risk management process. Factors used in the determination of special requirements include product or process complexity, experience and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of PMI's capacity, or requirements determined by PMI to be at the limit of its technical or process capabilities.

3.6 Risk

Risk is defined as an undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence. Risk analysis shall be performed on each job and completed within ten days after order acceptance (PMF-149).

Section 4: Context of the Organization

4.1 Understanding the Organization and its Context

PMI has a large customer base encompassing the following industries: aerospace & defense, heavy & light industrial, mining, oil & gas, power, public works, and schools.

PMI consists of four buildings: (1) East Bldg.-main office, laser inspection services, and small manual and CNC machinery (2) West Bldg.-engine shop and medium manual and CNC machinery (3) Froriep Bldg.-large CNC machinery (4) North (Aerospace) Bldg.-large CNC machinery and engineering services.

4.2 Needs and Expectations of Interested Parties

Customers are interested in the fact that we have a quality control system used in performing their work.

1) Customers that work with us because of our AS9100D require that we maintain that certification while their work is being completed. They expect us to provide all required quality-related paperwork and for us to include them in dispositions of

any nonconforming work. Some require that we pass their own audits. They expect their work to be done on time, per their specifications and at the agreed price.

2) The regulatory body (ABS Group) performs yearly audits of PMI and certifies that PMI conforms to AS9100D.
3) PMI employees expect that they will be given clear work instructions and adequate job training. They expect their paychecks to be correct and on time. They expect to have a safe and proper work environment.
4) Our external providers expect their purchase orders to be accurate. They also expect to be paid in a timely manner.
5) PMI managers at all levels expect to follow an approved management system to achieve results. They expect to have the required resources and to have access to competent workers. They also expect to have company expectations written down and followed.
6) Emergency responders and law enforcement personnel expect that we conduct business in a manner that keeps our employees safe. This includes federal occupational safety organizations such as OSHA and MSHA.
7) PMI meets statutory and regulatory requirements such as ITAR, the National Institute of Standards and Technology (NIST), and the US Cybersecurity Framework per the regulations of the federal government because we collect, store, and transmit controlled unclassified information (CUI). We are mandated to comply with the Gramm Leach Bliley Financial Modernization Act (GLBA) because we process certain consumer financial information including non-public, personal financial information (NPI).

4.3 Scope of the Quality Management System

PMI is a service and production organization providing services to a wide range of customers. We specialize in fabricating and machining and inspecting components for aerospace, defense, mining, power, and other industrial customers.

We provide machining, welding, laser inspection, and millwright services. We fabricate new components per customer requirements or repair others as requested. We provide in-shop and in-field services. We have some of the largest capabilities for a job-shop available anywhere.

Prime Machine, Inc. is located at:

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Salt Lake City, UT 84101

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PMI has a large variety of work that is performed in the shop. The customer purchase order will normally define expected delivery, level of quality documentation and inspection reporting required. If it does not, our project managers must define these requirements.

4.4 Quality Management System and its Processes

PMI has established, documented, and implemented a QMS to meet the requirements of SAE AS-9100D.

The system is maintained and continually improved by using the quality policy and objectives as the goal. Audit results, corrective & preventive action and management reviews help monitor progress towards the goal. PMI's QMS adheres to all customer and applicable statutory and regulatory QMS requirements.

Documentation was developed to show the QMS process interactions (See QFM-244). This document defines the QMS processes as: 1) contract review, 2) design and development 3) production/services, 4) purchasing and 5) management. The document discusses responsibility, risks, and opportunities as well as metrics used to assess the effectiveness of these processes.

The PMI QMS is composed of the following main documents. See QFM-205 Master Document Log for the complete list of governing documents.

QMS-001 Quality Manual

PMPs – PMI Procedures:

PJPs – Job Descriptions

PMFs – Forms and Flow Charts

PPCs – Process Procedure Controls

QFMs – Quality Forms

Each document is revision controlled. Each document has a document owner, who has the responsibility to review and ensure that their documents are relevant and up to date. The document owner, or the quality manager may initial and date the documents for approval.

PMP procedure documents are written to help implement the procedure in day-to-day operations, including the following clarifications:

1) Inputs and outputs expected from the process.
2) Interaction with other processes.
3) Criteria and methods (including monitoring, measurement, and related performance indicators) needed to ensure effective operation and process control.
4) Resources needed to carry out the process.
5) Assignment of responsibility and authority for the process.
6) Address risks and opportunities.

7) How to evaluate the process and implement changes to achieve intended results.

8) Steps to improve the process and the QMS.

9) Documentation required to support the operation of the process.

10) What documentation must be retained to show processes are being carried out as planned.

4.4.1 Quality Manual

This quality manual has been prepared to describe the PMI QMS. The scope of the QMS is described in Section 1. The interactions between the AS9100 Specification and PMI quality documents are found in QFM-244, located in the "PMI Quality Program" folder.

4.4.2 Control of Documents and Records

All of the QMS documents are controlled according to PMP-001 as follows:

- Approving documents for adequacy prior to issue.
- Reviewing and updating as necessary and re-approving documents.
- Ensuring that changes and current revision status of documents are identified.
- Ensuring that relevant versions of applicable documents are available for use.
- Ensuring that documents remain legible and readily identifiable.
- Ensuring that external documents are identified, and their distribution controlled.
- Preventing the unintended use of obsolete documents and applying suitable identification to them if they are retained for any purpose.

PMI coordinates document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

PMI quality records are maintained to provide evidence of conformity to QMS requirements. Quality records are maintained according to PMP-001. This procedure requires that quality records remain legible, readily identifiable, and retrievable. The procedure defines the controls needed for identification, storage, protection, retrieval, retention time and disposition of quality records.

The diagram in PMF-101 shows the process interactions between the main documents making up the PMI QMS.

4.4.2.1 Controlled Unclassified Information (CUI)

PMI is an entity that must meet the requirements of the National Institute of Standards and Technology (NIST) and the US Cybersecurity Framework per the regulations of the federal government because we collect, store, and transmit controlled unclassified information (CUI). We are mandated to comply with the Gramm Leach Bliley Financial Modernization Act (GLBA) because we process certain consumer financial information including non-public, personal financial information (NPI).

If any documents contain CUI, these documents will be controlled by PMI's information security and privacy program that includes technical, administrative, privacy and physical controls to meet these regulatory compliance requirements.

Section 5: Leadership

5.1 Leadership and Commitment

The PMI management team is actively involved in implementing the QMS. This team provides the vision and strategic direction for the QMS and establishes the quality objectives and the quality policy.

5.1.1 Management Responsibility

Management at PMI includes the chairman of the board, president, sales manager, directors, production managers, quality manager, chief financial officer, and human resources manager. To provide leadership and show commitment to the improvement of the QMS, top management will do the following:

- Take accountability for the effectiveness of the QMS.
- Establish the quality policy and quality objectives.
- Ensure the QMS integration into the organization's business processes.
- Promote the use of the process approach and risk-based thinking.
- Ensure the availability of resources for QMS.
- Communicate the importance of effective quality management.
- Communicate the importance of conforming to the QMS requirements.
- Ensure that the QMS achieves its intended results.
- Conduct management reviews as required to achieve planned results.
- Promote improvement.
- Support those in management roles to demonstrate their leadership.

5.1.2 Customer Focus

PMI strives to identify current and future customer needs, to meet customer requirements and exceed customer expectations.

Management shall demonstrate leadership and commitment by assuring that:

- Customer and statutory/regulatory requirements are met.
- Risks and opportunities affecting product and service conformity are addressed.
- Focus on enhancing customer satisfaction is maintained.
- Support those in management roles to develop their leadership abilities.
- Product and service conformity and on-time delivery performance are measured, and appropriate action taken if planned results are not, or will not be achieved.

5.2 Quality Policy

PMI quality policy: **"Solving society's complex challenges through engineering, machining, fabrication, and field services."**

To support this policy, we work to continually improve our people, technology, and processes in the following manner:

- **People:** PMI will always provide a secure and safe work environment. We encourage personal growth by providing opportunities for learning and improvement. We foster stewardship in our employees by requiring reporting and accountability.
- **Technology:** PMI continually researches, procures, and applies the latest technology and tooling to enhance our productivity, capability, and scope of services that we provide to our customers.
- **Processes:** PMI develops processes and procedures and then measures results to continually improve our products and services. Our leadership commits to comply with our QMS requirements and works to continually improve this system.

5.2.1 Establishing the Quality Policy

Top management ensures that the quality policy:

- Is appropriate to the purposes of PMI.
- Includes a commitment to comply with requirements and continually improve the effectiveness of the QMS.
- Provides a framework for establishing and reviewing quality objectives.
- Is communicated, understood, and applied within the organization.

5.2.2 Communicating the Quality Policy

Processes are established for documenting and communicating the quality policy within PMI.

The quality policy shall:

- Be available and maintained as documented information in the QMS on-line. It is also posted in several places throughout the shop.
- Be communicated and discussed in QMS training meetings so it is understood. It may also be communicated and discussed in staff meetings and management reviews.
- Be available to relevant interested parties, as appropriate.

5.3 Organizational Roles, Responsibilities and Authorities

5.3.1 Responsibility and Authority

An organization chart has been established to show the interrelation of personnel at PMI. Job functions and the organizational chart are reviewed and approved by top management for adequacy. This chart is available in "Organization Chart" folder in the "PMI Quality Program" folder to help employees understand lines of authority within the organization.

5.3.2 Management Representative

The quality manager has been appointed by the president as the management representative. As management's representative, the quality manager has the following responsibilities and authority:

- Ensure that the QMS conforms to the requirements of the international standards for AS9100.
- Ensure that the work processes are delivering their intended outputs.
- Report to top management on the performance of the QMS and note opportunities for improvement.
- Promote awareness of customer requirements throughout PMI.
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS.
- Assist with training regarding new procedures and revisions to existing procedures.
- Ensure that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.
- Resolve matters pertaining to quality or the departure from quality standards.
- Organizational freedom and unrestricted access to top management to resolve quality management issues.
- Fully responsible for implementing the calibration program at PMI. This includes defining the extent of the program, maintaining compliance with all procedures, and improving the program based on customer needs.
- In charge of QMS records retention.
- Product warranties.
- Root cause analysis and associated corrective actions.
- Continuous improvement throughout the company.

Section 6: Planning

6.1 Actions to Address Risks and Opportunities

6.1.1 Determine Risks and Opportunities

Risks and opportunities for jobs are determined by project managers during the contract review and risk analysis process. They are recorded in PMF-149 for each job. Risks and opportunities are also discussed in the management review meeting. The intent of this processes is to:

- Give assurance that the QMS can achieve its intended results.
- Enhance desirable effects.
- Prevent or reduce undesired effects.
- Achieve improvement.

6.1.2 Act on Risks and Opportunities

Project managers pass along risks and opportunities to production, external providers, and others who may need the information for specific jobs. Options to address risks can include avoiding risk, taking risks to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

Actions to address risks and opportunities from management review meetings are recorded and sent to the relevant individuals. The identified risks and opportunities may also integrate actions into our QMS. Quality metrics are updated as needed to evaluate the effectiveness of these actions.

Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address PMI's or its customer's needs.

QMS Process Interactions are shown in the diagram in QFM-244. The PMI QMS processes are: 1) Contract Review, 2) Production/Services, 3) Design and Development 4) Purchasing 5) Management. QFM-244 discusses responsibility, risks, and opportunities as well as metrics used to assess the effectiveness of these processes.

6.2 Quality Objectives and Planning to Achieve Them

6.2.1 Quality Objectives

Quality objectives are established to support our quality policy. They are reviewed at least annually for suitability. Objectives have been established for the following:

- Customer Satisfaction with Products and Services –

  We strive for **100% Customer Satisfaction** and measure this by a combination of surveys and input from our salesmen and project managers who are in contact with these Customers.

- Tracking On-time Delivery –

  Based on historical data, we think that 85% on-time delivery is achievable. Due to the nature of our business, there is continual scope change and delivery date

changes for many reasons. The on-time delivery date is based on the final date negotiated with the customer.

- Product Quality –

  Nonconforming products cost money. Our goal is to keep the cost of nonconformance below one percent of total gross revenue.

- Safety –

  A safe work environment is required to provide quality work. Our goal is to maintain an average EMOD less than1.0 and a TRIR of 2.5 or less. We also strive to have zero lost time accidents. This will ensure our employees will be safe while completing the necessary projects. (EMOD is an Experience Modifier Rating provided by our Workers Comp Insurance. TRIR is the Total Recordable Incident Rating - calculated by multiplying the Total number of OSHA Recordable Accidents by 200,000 and dividing by the total number hours worked at PMI during the year.)

These quality objectives are consistent with the quality policy, measurable, monitored and discussed at management review meetings.

The quality manager maintains documented information relating to the quality objectives and shall also ensure the objectives are updated, relevant and communicated to all within the company.

6.2.2 Quality Management System Planning

The PMI QMS has been planned and implemented to meet company quality objectives and the requirements of the AS9100D standard.

The integrity of the QMS shall be maintained when changes to the QMS are planned and implemented.

When planning how to achieve the quality objectives, the organization shall determine:

- What will be done.
- What resources will be required.
- Who will be responsible.
- When it will be completed.
- How the results will be evaluated.

6.3 Planning of Changes

When PMI determines the need for changes to the QMS, the changes shall be carried out in a planned manner, considering the following:

- Purpose of the changes and their potential consequences.
- Integrity of the QMS.
- Availability of resources.
- Allocation or reallocation of responsibilities and authorities.

Section 7: Support

7.1 Resources

7.1.1 General

PMI has implemented a QMS that complies with AS9100D standards. This was achieved with management commitment to provide sufficient resources and to effectively maintain and continually improve the system.

7.1.2 Human Resources

To ensure competence of our personnel, new employees are hired based on their education, skills, and experience within applicable industries. New employees are given an orientation by their area manager, which includes an introduction of the PMI QMS. The area manager provides on-the-job training to the new employee and evaluates the new employee's performance to determine their competence.

Employee qualifications are reviewed before hire, when an employee changes positions or when the requirements for a position change. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job. Detailed job descriptions (see PJP documents) are available for all work positions.

An evaluation of the training and its effectiveness will be done before the employee is deemed competent to perform work affecting conformity to product requirements. All employees are trained in the relevance and importance of their activities and how they contribute to the achievement of the quality objectives. Appropriate records of education, training, skills, and experience will be maintained as applicable.

7.1.3 Infrastructure

To meet quality objectives and product requirements, PMI management has determined the infrastructure required. The infrastructure includes buildings, workspace, utilities, process equipment (both hardware and software) and supporting services (such as transportation, communication, and information systems).

As new infrastructure requirements arise, they will be documented in the management review and regular staff meetings. Existing infrastructure is maintained as required (see QFM-501).

7.1.4 Work Environment

A work environment suitable for achieving product conformance is maintained. Job requirements are determined during the contract review.

Data from the quality system is evaluated to determine if the work environment is adequate to achieve product conformance or if corrective action related to the work environment is required.

Work environment factors include temperature, lighting, cleanliness, etc. They also include social (non-discriminatory, non-confrontational, etc.) and psychological (stress-reducing, burnout prevention, etc.) components.

7.1.5 Monitoring and Measuring Resources

7.1.5.1 Validation of Monitoring and Measuring Equipment

PMI quality manager shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

Any special monitoring, measurement, or validation requirements are to be defined in the work order router (see PMP-003).

PMI ensures that resources provided are:

- Suitable for the specific type of monitoring and measurement activities being undertaken.
- Maintained to ensure their continuing fitness for their purpose.

Appropriate documented information shall be retained as evidence of fitness-for-purpose of the monitoring and measurement resources.

7.1.5.2 Measurement Traceability

PMI quality manager will determine the required monitoring and measurements to be undertaken during the manufacture of each component specified in the work order router.

PMI maintains a register of standard monitoring and measuring devices and has defined the process employed for their calibration and use (see PPC-556). This register includes equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.

Monitoring and measuring devices may include, but are not limited to test hardware, test software and automated test equipment (ATE). It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.

PMI ensures that environmental conditions are suitable for the calibrations, inspections, measurements, and tests being carried out.

Where necessary to ensure valid results, measuring equipment is:

- Calibrated or verified at specified intervals against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded.
- Adjusted or re-adjusted as necessary.
- Identified to enable the calibration status to be determined.
- Safeguarded from adjustments that would invalidate the measurement result.

- Protected from damage and deterioration during handling, maintenance, and storage.
- PMI has implemented and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification.

In addition, during each calibration interval, if a tool is found to be out of calibration, PMI takes appropriate action on the equipment and any product thought to be affected.

7.1.6 Organizational Knowledge

PMI top management shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

When addressing changing needs and trends, the company shall consider its current knowledge, and determine how to acquire or access any necessary additional knowledge or required updates.

Organizational knowledge is specific to the company and is generally gained by experience. It can be based on:

- Internal Sources – Intellectual property, experience, lessons learned, things learned by employees through any method, and results gathered from improvements in processes, products, and services.
- External Sources – standards, schools, conferences, customers, external providers etc.

7.2 Competence

PMI management shall:

- Determine the necessary competence of workers that affect the performance and effectiveness of the QMS.
- Ensure that these workers are competent based on appropriate education, training, or experience.
- Where applicable, take actions to acquire the necessary competence and evaluate the effectiveness of the actions taken.
- Retain appropriate documentation as evidence of competence.
- Periodically review the necessary competence.
- Act to train, mentor or reassign employees as necessary.
- Hire or contract with the necessary competent people.

7.3 Awareness

The Quality Manager shall make sure that employees are aware of:

- The quality policy.
- Relevant quality objectives.
- Their contribution to the effectiveness of the QMS, including the benefits of improved performance.
- The implications of not conforming with the QMS requirements.

- Relevant QMS documented information and changes thereto.
- Their contribution to product or service conformity and safety.
- Their contribution to safety in the workplace.
- The importance of ethical behavior.

7.4 Communication

PMI quality manager shall determine the internal and external communications relevant to the QMS including:

- On what it will communicate.
- When to communicate.
- With whom to communicate.
- How to communicate.
- And who communicates.

Communication should include internal and external feedback relevant to the QMS.

7.5 Documented Information

7.5.1 General

PMI's QMS shall include:

- Documented information required by AS9100D Standard
- Documented information determined by PMI to be necessary for QMS effectiveness.

The extent of this documented information shall remain based on the organization size, type of activities, processes, products, and services. It shall also be based on the complexity of processes and their interactions as well as the competence of current employees.

7.5.2 Creating and Updating Documented Information

When creating and updating documented information, we shall ensure appropriate:

- Identification and Description (title, date, author, reference number, etc.)
- Format (language, software version, graphics) and media (paper, electronic, etc.)
- Review and approval for suitability and adequacy.

Authorized persons and approval methods are to be identified for the relevant types of documented information. Document history is tracked using QFM-205. Control of documents follows standards in PMP-001.

7.5.3 Control of Documented Information

Documented information required for the QMS and AS9100D standard shall be controlled to ensure:

- It is available and suitable for use, where and when it is needed.
- It is adequately protected (from loss of confidentiality, improper use, or loss of integrity)

For the control of documented information, PMI shall address the following activities as applicable:

- Distribution, access, retrieval, and use (see PMP-001),
- Storage and preservation, including preservation of legibility.
- Control of changes (version control).
- Retention and disposition.
- Prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

Documented information of external origin, which has been determined to be necessary for the planning and operation of the QMS, shall be identified as appropriate and be controlled.

Documented information retained as evidence of conformity shall be protected from unintended alterations.

When documented information is managed electronically, data protection processes shall be defined (protection from loss, unauthorized changes, unintended alteration, corruption, physical damage, etc.)

Section 8: Operation

8.1 Operational Planning and Control

PMI management shall plan for and implement the following actions, to the extent required for each individual job:

- Determine the requirements for the product or service, including:
    - Product and personal safety.
    - Producibility and inspectability.
    - Reliability, availability, and maintainability.
    - Manufacturability and ease of inspection.
    - Suitability of parts and material used in the product.

- Product obsolescence.
- Prevention, detection, and removal of foreign objects.
- Handling, packaging, and preservation.
- Recycling or final disposal of the product at the end of its life.

- Establish criteria for the processes.
- Establish criteria for product acceptance.
- Determine the resources needed to achieve conformity to requirements and to meet on-time delivery.
- Control of the processes in accordance with the criteria.
- Determine, maintain, and retain documented information sufficient to have confidence the process has been carried out as planned and to demonstrate the conformity to requirements.
- Determine the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified.
- Engage area managers for operational planning and control.
- Determine the process and resources to support the use and maintenance of the products and services.
- Determine the products and services to be obtained from external providers and ensure that outsourced processes are controlled as necessary.
- Establish controls to prevent the delivery of nonconforming products and services to the customer.
- Ensure configuration management is appropriate to the products.
- Establish, implement, and maintain a process to plan and control the temporary or permanent transfer of work, and ensure work transfer impacts and risks are understood and managed.

Planning output shall be in conformance with PMP-003.

Planning documents specifying processes and/or QMS, and the resources to be applied to a specific product, project, or contract, can be referred to as a quality plan. This quality plan should travel with the work order packet.

8.1.1 Operational Risk Management

PMI management shall plan, implement, and control a process for managing operational risks (see PMP-009) to achieve applicable requirements that may include:

- Assignment of responsibilities for operational risk management.
- Definition of risk assessment criteria (likelihood, consequences, risk acceptance).
- Identification, assessment, and communication of risks throughout operations.

- Identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria.
- Acceptance of risks remaining after implementing mitigating actions.

Risk is generally expressed in terms of the likelihood of occurrence and the severity of consequences.

A document has been made to show possible risks and opportunities associated with the production/services process (see QFM-243). This shows an approach to better understand this process.

Operational risks shall be identified before accepting orders (new technology, ability, and capacity to provide results, short delivery time, etc.) We need to know that we can meet the claims we make for the products and services offered (see PMF-149). It is expected that this form be used before each job as an aid in assessing risk.

8.1.2 Configuration Management

PMI quality manager shall plan, implement, and control a configuration management process that ensures the identification and control of physical and functional attributes throughout the product lifecycle (see PMP-008) This process shall:

- Control product identity and traceability, including the implementation of identified changes.
- Ensure that the documented information (requirements, design, verification, acceptance documentation and validation) is consistent with the actual attributes of the products and services.

8.1.3 Product Safety

PMI Management shall plan, implement, and control the processes needed to assure product safety during the entire product life cycle, as appropriate to the product. This may include:

- Assessment of hazards and management of associated risks.
- Management of safety critical items.
- Analysis and reporting of events that have occurred affecting safety.
- Communication of these events and training of employees.

8.1.4 Prevention of Counterfeit Parts

PMI has processes in place to prevent counterfeit or suspected counterfeit part use and their inclusion in products delivered to the customer (see PMP-004). Counterfeit part prevention includes:

- Acquiring externally provided products from OEMs, authorized distributors, or other approved sources.

- Requirements for assuring traceability of parts and components to their original or authorized manufacturers.
- Any other measure that makes sense for the types of products we produce.

Materials are reviewed by the receiving department when delivered. The receiving department checks quality, quantity, certs, and looks for anything that may appear unusual or indicate counterfeit, see PMF-103.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

PMI project managers are always in close contact with our customers. As an order progresses through the manufacturing cycle, the customer is kept up to date on progress and problems. Regular communication with the customer is maintained in the following areas:

- Product and service information.
- Inquiries, contracts, and order handling, including changes or amendments.
- Customer feedback, including customer complaints.
- Handling or controlling customer property.
- Establishing requirements for contingency actions, when relevant.

8.2.2 Determining Requirements for Products and Services

PMI project managers determine customer requirements before acceptance of an order. Product or service requirements may include:

- Statutory and regulatory requirements related to the product.
- Requirements considered necessary by PMI.
- Requirements requested by the customer.
- Customer specifications or other standards.
- Any special requirements.

8.2.3 Review of Requirements for Products and Services

PMI sales manager has a process in place for the review of requirements related to the product and services we provide (see PMF-102 and PMF-149).

The review is conducted before the order is accepted. The process ensures that:

- Customer requirements are reviewed.
- Plans are in place for identifying and planning statutory and regulatory requirements.

- Contract or order requirements differing from those previously expressed are resolved.
- PMI can meet the defined requirements.
- Special requirements of the product are determined.
- Risks (new technology, short delivery time frame) have been identified.
- Known risks have been adequately identified and planned for along with assessment of other risks such as new technology implementations or process and/or schedule changes.
- Records are maintained showing the results of the review and any actions arising from the review. Where a customer does not provide a documented statement of requirement, the customer requirements shall be confirmed before acceptance.

8.2.4 Changes to Requirements for Products and Services

When product requirements are changed, PMI shall communicate changes to relevant personnel and amend relevant documents.

8.3 Design and Development of Products and Services

Design and development of products by PMI falls into two categories: Method 1 the design is initiated, and outputs defined by others and Method 2 the design is initiated, and outputs defined by PMI.

- Method 1 – Entails customer specified output which the PMI design requirements are specified within the customer PO.
- Method 2 – Entails customer specified output by PMI – Not applicable currently.

8.3.1 General

All PMI designed products shall follow a standard development process which consists of the following stages:

- Initiate – After the decision is made to go forward with a job either by a customer PO or PMI business decision, the job is to be evaluated for viability, scope, outputs, resources, time frame, and risk.
- Planning – After a job has been initiated work begins to develop a schedule and assign resources in a work order which is input to GSS.
- Execution – Work on a job begins after the team has been brought together for a kickoff meeting where schedule, requirements and resources are discussed. Execution is to consider all required design activities to ensure the final design meets fit, form, and function as well as a safety review. During the job execution stage, the following reviews and outputs shall be followed:
    - Design.
    - Validation calculations.

- Drawings.
- Drawings and calculations peer review.
- If necessary, required testing validation of actual product.

- Monitoring and Control – The design process is to be followed by either the engineer and/or project manager to understand and approve all changes. All changes are to be documented, changes that occur after the design and drawing have been approved must use an Engineering Change Notification (ECN) form, QFM-255.
- Close Out – The design portion of the job closes when the customer outputs are complete, and the customer has reviewed and approved the design.

8.3.2 Design and Development Planning

The following shall be included as part of the planning stage:

- The project manager is responsible for kicking off the job design activities.
- PMI management will determine when a job has evolved enough and requires a controlled design. This is typically decided when a job appears to have a high likelihood of being fabricated. Prior to this decision, any R&D activity is outside the scope of the management system.
- After PMI management's approval to move forward the job is initiated, and a project manager will be assigned, and the job will be entered into GSS and begin to be planned. GSS output is the work order. The work order shall consist of distinct sequences outlining tasks, resources, design requirements as well as expected inputs and outputs. See PMP-003 Creation or Routers for details about writing work orders.
- The design planning documentation is recorded in GSS. This will include the assigned design engineer(s), support staff, subordinate third-party provider(s), and the responsibility and authority for each. Where third parties are utilized, this shall define the approved points of contact.
- The project manager will develop a design schedule; this will be developed with the input of the customer and third-party provider(s), if necessary. The schedule will be updated by the project manager as the design work progresses.
- The level of control expected from the customer and the expectation for documented information should be determined at the project beginning. Clear expectations make it easier to successfully complete a project.
- The ability of our company to provide sufficient resources to accomplish all the requirements of the design and development project shall be considered. This is normally done in the contract review stage.

8.3.3 Design and Development Inputs

The following shall be included as part of the inputs stage:

- Design “inputs” are the requirements for the final product.
- The engineer and/or project manager shall define and understand all requirements related to the product. These may include:
  - Customer requirements.
  - Regulatory and statutory requirements.
  - Lessons learned from similar jobs in Company history.
  - Internal requirements (capabilities, capacities, etc.).
  - Safety requirements, as applicable.
  - Human factors, as applicable.
  - Measurement and inspection methods, acceptance criteria and tolerances.
  - Applicable third-party specifications, standards, etc.
  - Material requirements.
  - Functional requirements.
  - Cost.
  - Manufacturability of items.
  - Consequences of potential failure of products and services.
- The design inputs will be captured in the work order.
- Design inputs that cannot be captured in the work order will be documented and saved in the job folder.
- The inputs shall be adequate and expectations clear. Conflicts shall be resolved.

8.3.4 Design and Development Controls

A The following shall be included as controls:

- The design outputs must undergo two types of review. The first is a simple design review performed by the detailer of the design output (who may review their own work). Based on the design planning performed earlier, additional reviews may include signed off by an objective third-party. Review shall evaluate whether the design can fully meet requirements.
- Next, design verification shall be performed. This is a verification that all design inputs have been addressed satisfactorily in the design outputs. This is conducted by the project engineer and/or the project manager. Records of design verification are maintained in the job file in the engineering folder.
- The design process may not proceed until all design outputs are verified as having addressed the design inputs.

- Design validation is conducted by comparing the design outputs with requirements specified by the project manager and the customer.
- Written authorization to proceed from stage to stage is required. This may include signatures on drawings, engineering calculations, and engineering change notices (ECNs).

8.3.4.1 Design and Development Testing

If testing is ever required for verification or validation, the tests shall be planned, controlled, reviewed, and documented. Testing shall follow the guidance shown:

- Test plans shall identify the test item, resources required, objectives, conditions, parameters to be recorded, and the acceptance criteria.
- Test procedures shall describe testing methods, how to perform the test, and how to record the results.
- The correct configuration of the test item is to be used.
- Requirements of the test plan and procedures shall be observed.
- The acceptance criteria are met.
- Any monitoring and measuring instruments used shall be calibrated per section 7.1.5.
- Reports made at the end of testing shall show whether the design meets the specification requirements at the identified operational conditions.

8.3.5 Design and Development Outputs

The following shall be included as part of the outputs:

- Once design inputs are captured, the production of design outputs may begin. Typically, these include:
  - Models
  - Drawing
  - Calculations
  - Specifications
- The project engineer and/or project manager will oversee the development of the appropriate design outputs, including those produced by third-party providers.
- All design outputs must be developed so they properly address the applicable design input requirements.

- Outputs shall be adequate for manufacturing products or providing services.
- Outputs shall reference the use of calibrated measuring or monitoring devices and shall define acceptance criteria (correct fits, tolerances, etc.) as appropriate. Key characteristics and required actions shall be defined as appropriate.
- Written authorization to proceed from stage to stage is required. This may include signatures on drawings, engineering calculations, and ECNs.
- PMI shall define the data required to allow the product to be identified, manufactured, verified, used, and maintained, including as necessary: drawings, part lists, specifications, configurations, materials required, processes to be used, packaging, etc.

We are required to retain documented information on design and development outputs.

8.3.6 Design and Development Changes

The following shall be included when changes are made:

- Where changes are required of design data, these shall be requested by submitting the change to both the engineer and project manager.
  - Engineers evaluate feasibility and design impact.
  - Project manager evaluates scope and cost impact.
- The change request will be reviewed by the engineer and/or project manager and if approved, shall then be implemented using ECN form QFM-255.
- Applicable design data and/or documents will be revised with their revision indicator incremented per the ECN.
- Changed designs require the same design review, verification, and validation as original releases.
- We shall retain documented information in the Project Folder in the Engineering sub-Folder.

8.4 Control of External provider Processes, Products and Services

8.4.1 Purchasing Process

A documented control procedure for purchasing (see PMP-004) is followed to ensure that purchased product conforms to the specified requirements. The procedure outlines the extent of control required for external providers and the purchased product or service. PMI is responsible for the quality of products purchased from all external providers, including customer-designated sources.

External providers are evaluated and selected based on their ability to supply product in accordance with requirements. Criteria for selection, evaluation and re-evaluation are

documented. Records of the evaluation and any necessary actions are maintained. PMI purchasing manager will do the following:

- Maintain a register of approved external providers that includes the approval status (approved, conditional, disapproved) and the scope of the approval (product type or process family).
- Require that external providers apply appropriate controls to their direct and sub-tier external providers to ensure that requirements are met.
- Periodically review external provider performance (including process, product and service conformity, and on-time delivery performance) and retain documented information from these reviews; records of these reviews are used as a basis for establishing the level of controls implemented (see PMP-004).
- Define the necessary actions to take when dealing with external providers that do not meet requirements (see PMP-007).
- Ensure where required that both PMI and all external providers use customer-approved special process sources.
- Define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of external providers depending on the external provider's approval status.
- Determine and manage risk when selecting and using external providers.
- Define requirements for controlling documentation created by and/or retained by our external providers.

  NOTE: One factor that can be used during external provider selection and evaluation is quality data from objective and reliable external sources (information from accredited QMS or certification bodies, for example, ISO-9001 accreditation).

8.4.2 Type and Extent of Control

PMP-004 describes the processes used to verify that purchased product meets specified requirements. PMI purchasing manager will do the following:

- Ensure that externally provided processes remain within our QMS.
- Define controls applied to external providers and to output from those external providers.
- Consider the impact of external provider products or services on meeting our customer's requirements.
- Consider the effectiveness of controls applied by our external providers.

- Determine the verification necessary to ensure external provider supplied products and services meet our requirement. This is based on any risks identified and may include inspection or testing.
- Obtain and review objective evidence of the quality of the product from external providers (accompanying documentation, certificate of conformity, test reports, statistical records, and process control).
- Audit our external providers (see QFM-202) and review the results. Inspect external provider premises as deemed necessary by the purchasing manager.
- Inspect products from external providers upon receipt per project manager request (see PMP-004 for details).
- Review any required product verifications delegated to our external providers.

When a purchased product is released for production before completion of all required verification, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product did not meet requirements.

Customer verification activities do not absolve PMI of its responsibility to provide acceptable products and comply with requirements.

When PMI utilizes test reports to verify purchased products, we shall evaluate the data in those reports to make sure it meets our customer's requirements. PMI shall periodically validate test reports for raw material if any potential risk has been identified.

If PMI delegates verification activities to an external provider, the requirements for delegation are defined and a register of delegations shall be maintained.

8.4.3 Information provided to External Providers

Purchasing documents are to be reviewed to ensure the adequacy of requirements before orders are placed with an external provider.

Purchasing information shall describe the product or service to be purchased, including where appropriate:

- Identification of relevant technical data (specifications, drawings, process requirements, work instructions, etc.).
- Requirements for approval of product, processes, equipment, and services.
- Requirements for qualification of personnel (if relevant).
- Any special requirements for external provider interactions with PMI.
- Any special external provider controls or monitoring required by PMI.
- Any verification or validation that PMI or its customer may need to perform at the external provider's premises.
- Any special requirements, critical items, or key characteristics.

- Requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by PMI.
- The need to implement a QMS.
- The need to use approved external providers (if necessary).
- Requirements to notify PMI of nonconforming product, obtain PMI approval for nonconforming product, notify PMI of changes in product and/or process, changes of external providers, changes of manufacturing facility location and, where required, obtain PMI approval and, flow down to the supply chain the applicable requirements, including customer requirements.
- Requirements for test specimens (production method, number, storage conditions) for design approval, inspection, investigation, or auditing.
- Record retention requirements.
- Right of access by PMI, its customer, and regulatory authorities to all facilities involved in the order and to all applicable records.
- Reminder to the external provider of their contribution to product or service conformity, safety, and of the importance of ethical behavior.
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8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

PMI production manager implements production and service provision under controlled conditions. Controlled conditions may include, as applicable:

- The availability of information that describes the characteristics of the product, services to be provided, activities to be performed and the results to be achieved. This information may include drawings, parts lists, materials, and process specifications. It may also include process flow charts, control plans, production documents (manufacturing plans, routers, work orders, etc.).
- The availability and use of monitoring and measuring devices.
- The implementation of monitoring and measurement to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met, including:
  - Criteria for acceptance and rejection.
  - Where verification operations are performed in sequence.
  - Measurement results to be retained (at least acceptance or rejection).
  - Any specific equipment required and instructions for their use.

- The use of suitable infrastructure and environment for the operation of processes (jigs, fixtures, software, etc.).
- The use of competent people, including any required qualifications.
- Validation of the ability to achieve planned results – where resulting output cannot be verified by subsequent monitoring or measurement.
- Implementation of actions to prevent human error.
- The implementation of product release, delivery, and post-delivery activities.
- Criteria for workmanship (acceptance or rejection), which shall be stipulated in the clearest practical manner (written standards, representative samples, or illustrations).
- Accountability for all products during manufacture (parts quantities, split orders, nonconforming product).
- Establishing, implementing, and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified.
- Determination of methods to measure variable data (tooling, on-machine probing, inspection equipment, etc.)
- The identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization.
- Evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized.
- Provision for the prevention, detection, and removal of foreign objects.
- Monitoring and control of utilities and supplies such as water, compressed air, electricity, and chemical products to the extent they affect conformity to product requirements.
- Identification and recording of products released for subsequent production before completion of all required measuring activities. This allows recall and replacement if it is later found that the product does not meet requirements.

8.5.1.1 Control of Equipment, Tools, and Numerical Control (NC) Programs (software)

Production equipment, tools and software programs used to automate, and control/monitor product realization processes are validated prior to release and are maintained and inspected periodically according to documented procedures. Validation prior to production use includes verification of the first article produced to the design data/specification.

Storage requirements, including periodic preservation/condition checks, are defined for production equipment or tooling in storage.

8.5.1.2 Validation and Control of Special Processes

For processes where the resulting output cannot be verified by subsequent monitoring or measurement, PMI shall arrange for these processes including, as applicable:

- Definition of criteria for the review and approval of the processes.
- Determination of conditions to maintain the approval.
- Approval of facilities and equipment.
- Qualification of personnel.
- Use of specific methods and procedures for implementation and monitoring the processes.
- Requirements for documented information to be retained.

8.5.1.3 Production Process Verification

PMI will use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling can produce parts and assemblies that meet requirements.

This process shall be repeated when changes occur that invalidate the original results (engineering changes, manufacturing process changes, tooling changes). This activity is often referred to as First Article Inspection. Documented information shall be retained showing the results of the production process verification.

8.5.2 Identification and Traceability

PMI identifies the product throughout product realization in accordance with PMP-003. The work order is the primary document for identifying all identification requirements and capturing all traceability needs.

PMI maintains the identification of the configuration of the product to identify any differences between the actual configuration and the required configuration.

PMI identifies the product status with respect to monitoring and measurement requirements throughout product realization.

PMI controls, records, and retains the unique identification of the product wherever traceability is a contract specified requirement. The specific method of identification will be determined on a case-by-case basis and will be defined in the work order.

When acceptance authority media are used (stamps, passwords, etc.) PMI shall establish appropriate controls for the media.

According to the level of traceability required by contract, regulatory or established requirement, PMI's system provides for:

- Identification to be maintained throughout the product life.

- All the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch.
- An assembly, the identity of its components and those of the next higher assembly to be traced.
- A given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.

8.5.3 Customer or External Provider Property

PMI exercises care with customer property while it is under PMI's control or use.

Control of customer property is outlined in PMP-005 and PMP-007.

If any customer property is lost, damaged, or otherwise found to be unsuitable for use, this is reported to the customer and records maintained.

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

8.5.4 Preservation of Product

PMI preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

This preservation may include identification, contamination control, handling, packaging, storage, transmission or transportation and protection.

Preservation of product may include:

- Cleaning.
- Prevention, detection, and removal of foreign objects.
- Special handling for sensitive products.
- Marking and labeling including safety warnings.
- Shelf-life control and stock rotation.
- Special handling for hazardous materials.

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

8.5.5 Post-Delivery Support

PMI shall meet requirements for post-delivery activities associated with products and services. In determining the extent of post-delivery support, the following shall be considered:

- Statutory and regulatory requirements: We normally determine any post-delivery statutory and regulatory requirements during the contract review.

- Potential undesired consequences associated with the products and services: This may include problems associated with repairs we make to customer components or with reverse engineering where mistakes are very easily made.
- Nature, use, and intended lifetime of the products and services: For make to print jobs, we do not track this information. We do not make any of our own products. If we do reverse engineering of customer components, we stay connected with customers using our products to make sure of fit and function. This can become a warranty issue if the product does not fit or function.
- Customer requirements: We normally determine any post-delivery customer requirements during the contract review.
- Customer feedback: We send out customer satisfaction questionnaires (PMF-158). Otherwise, our salesmen and project managers are responsible for determining and reporting our company's standing with customers.
- Collection and analysis of in-service data (performance, reliability, lessons learned): All PMI products and/or services are sent to the customer for future or immediate use. We are unable to track performance or reliability on our own. We rely on our customer to provide feedback.
- The control and updating of technical documentation relating to product use, maintenance, repair, and overhaul: We do not provide any product or service requiring technical documentation.
- Controls required for work undertaken external to the organization (off-site work): All fieldwork is completed by our sister company – Prime Field Service.
- Product/customer support (queries, training, warranties, maintenance, replacement parts, resources, obsolescence, etc.): We provide a warranty (QFM-235) covering labor and materials. We contract out maintenance and in-field installation and repairs through Prime Field Service. We provide spare parts either by using customer drawings or by providing reverse engineering services.

When problems are detected after delivery, PMI shall take appropriate action including investigation and reporting. This need is normally determined by our customer or by Prime Field Service. Phone calls or emails from customers typically come to the project manager or salesman initially responsible for the job. If they come to our front office or president, they are routed to the correct project manager. If the component needs to be repaired in the shop, the project manager provides shipping instructions to the customer and the project manager or receiving department will mark the component with a job number once it is delivered to our shop. Repairs are documented with a work order in our GSS ERP System. The job number is normally the same as when the component was originally made in the shop with a new dash number assigned.

Any details regarding the nonconformance are documented per PMP-007 and stored in our network job folder. The project manager determines whether we will charge

the customer for the problem or if we will provide repairs under warranty. This is typically documented with an e-mail to the customer along with a phone call. This e-mail is to be stored in the network job folder along with any other pertinent information provided.

Since all products made by PMI are custom per a customer purchase order, we do not take parts back into stock. We will decide at the time we are notified of a problem what actions are to be taken. This is normally done by the project manager. The project manager works closely with the quality manager to make sure warrantied work is tracked by cost of quality, and to make sure NCRs are created, as necessary.

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

8.5.6 Control of Changes

PMI shall review and control changes for production or services, to the extent necessary to ensure continuing conformity with requirements, see PMP-003.

Persons authorized to approve changes to production shall be identified.

PMI shall retain documented information describing the results of the review of changes, the people authorizing the change and any actions arising from the review.

8.6 Release of Products and Services

PMI shall make planned arrangements to verify that the product and service requirements have been met.

The release of products and services to the customer shall not proceed until these arrangements have been completed, unless otherwise approved by a relevant authority or the customer, see QFM-219.

PMI shall retain documented information on the release of Products and Services. This shall include:

- Evidence of conformity with the acceptance criteria.
- Traceability to the person authorizing the release.

PMI shall ensure that retained documents provide the evidence required to show product conformity. All required documentation shall be present at delivery.

8.7 Control of Nonconforming Outputs

8.7.1 Identification of Nonconforming Outputs

PMI ensures that products which do not conform to product requirements are identified and controlled to prevent their unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in PMP-007.

NOTE: The term “Nonconforming Product” includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.

PMI’s documented procedure defines the responsibility for review and authority for the disposition of nonconforming products and the process for approving personnel making these decisions.

PMI deals with nonconforming product in one or more of the following ways:

- By taking action to correct the detected nonconformity.
- By authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable, by the customer.
- By segregating, containing, returning, or suspending products or services.
- By informing the customer.
- By acting appropriately to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.
- PMI’s nonconforming product control process provides for timely reporting of delivered non-conforming product: Note: Parties requiring notification of nonconforming product can include external providers, internal organizations, customers, distributors, and regulatory agencies.
- By taking actions necessary to contain the effect of the nonconformity on other processes or products.

PMI does not use dispositions of use-as-is or repair unless it is approved by an authorized representative of the organization responsible for the design.

Note: Authorized representative includes personnel having delegated authority from the design organization.

PMI does not use dispositions of use-as-is or repair unless specifically authorized by the customer if the nonconformity results in a departure from the contract requirements.

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

Records of the nature of nonconformities and any subsequent action taken, including concessions obtained, are maintained.

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

Counterfeit, or suspected counterfeit parts, shall be controlled to prevent reentry into the supply chain.

8.7.2 Documentation of Nonconforming Output

PMI retains documented information in a nonconformance report, see QFM-201. Nonconformance reports include information that:

- Describes the nonconformity.
- Describes the Actions taken.
- Describes any concessions obtained.
- Identifies the authority deciding the action in respect to the nonconformity.

Section 9: Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

PMI shall determine:

- What needs to be monitored and measured.
- Methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results.
- When the monitoring and measuring shall be performed.
- When the results from monitoring and measurements shall be analyzed and evaluated.

PMI shall evaluate the performance and effectiveness of the QMS.

PMI shall retain appropriate Documented Information as evidence of the results.

9.1.2 Customer Satisfaction

The PMI sales manager shall monitor information relating to customer perception as to whether PMI has fulfilled customer requirements.

Information that is monitored and used for the evaluation of customer satisfaction includes product and service conformity, on-time delivery performance, customer complaints and corrective action requests.

Monitoring customer perception may include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, PMI salesmen feedback, compliments, warranty claims and dealer reports. PMI has a standardized email survey to be used for customer feedback.

PMI shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by the above evaluations and assess the effectiveness of the results.

9.1.3 Analysis and Evaluation

The data gathered shall be analyzed and evaluated. The results of the analysis shall be used to evaluate:

- Conformity of products and services.
- Degree of customer satisfaction.
- Performance and effectiveness of the QMS.
- Whether planning has been implemented effectively.
- Effectiveness of actions taken to address risks and opportunities.
- Performance of external providers.
- Need for Improvements to the QMS.

9.2 Internal Audit

9.2.1 Audit Intervals

PMI Quality Manager conducts internal audits at planned intervals to determine whether the QMS:

- Conforms to PMI's own requirements for the QMS.
- Conforms to the AS9100D Standard.
- Is effectively implemented and maintained.
- Performance indicators show the QMS is effectively implemented and maintained.

9.2.2 Audit Details

An audit program has been designed and implemented, see PMP-006. This procedure includes the following items:

- Plan, establish, implement and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting which shall take into consideration the importance of the processes concerned, changes affecting the organization and the results of previous audits, see QFM-228.
- Define the audit criteria and scope for each audit.
- Select auditors and conduct audits to ensure objectivity and the impartiality of the audit process.
- Ensure that the results of the audits are reported to relevant management.

- Take appropriate correction and corrective actions without undue delay.
- Retain documented information as evidence of the implementation of the audit program and the audit results.

Auditors shall not audit their own work. Records of the audits and their results are to be maintained.

9.3 Management Review

Top management reviews the QMS manual at management review meetings normally held twice yearly. This review assesses the continuing QMS suitability, adequacy, and effectiveness, identifying opportunities for improvement and needed changes, including the quality policy and quality objectives. Records shall be maintained for each Management Review Meeting.

9.3.1 General

Top Management shall review the organization's QMS at planned intervals to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of the Organization, see PMF-127.

9.3.2 Management Review Inputs

Management Review shall be planned and carried out taking into consideration:

- Status and actions from previous management reviews.
- Changes in external and internal issues relevant to the QMS.
- Information on performance and effectiveness of the QMS.
- Customer feedback.
- Extent to which quality objectives have been met.
- Process performance and conformance of products and services.
- Monitoring and measuring results.
- Status of preventive and corrective actions.
- Results of audits.
- Scrap and rework costs.
- Performance of external providers.
- On-time delivery performance.
- Adequacy of resources.
- Effectiveness of actions taken to address risks and opportunities.
- Planned changes that could affect the QMS.
- Recommendations for improvement.

9.3.3 Management Review Output

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

- Improvement of the effectiveness of the QMS and its processes.
- Opportunities for improvement of products or services.
- Resource needs.
- Risks that have been Identified.

Responsibilities for required actions are assigned to members of the staff in attendance. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the management review minutes. This document shall be retained.

Section 10: Improvement

10.1 General

PMI shall determine and select opportunities for improvement and implement any necessary actions to meet Customer requirements and enhance satisfaction by:

- Improving products and services to meet requirements as well as to address future needs and expectations.
- Correcting, preventing, or reducing undesired effects.
- Improving the performance and effectiveness of the QMS.

NOTE: Improvement could include corrections, corrective action, continual improvement, breakthrough change, innovation, and re-organization.

10.2 Nonconformity and Corrective Action

PMI takes action to eliminate the cause of nonconformities to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered, see QFM-201. Corrective actions are documented and stored in the “Corrective Actions” folder on the network.

10.2.1 Nonconformity Actions Required

When nonconformity occurs, the PMI shall:

- Review nonconformities (including customer complaints).
- React to the nonconformity and take action to control and correct it.
- Deal with and manage the consequences.
- Review and determine the causes of nonconformity.
- Evaluate causes related to human factors.
- Determine if similar nonconformities exist or could potentially occur.
- Evaluate the need for action to ensure that nonconformities do not recur.

- Determine and implement actions needed.
- Record the results of corrective actions taken.
- Update risks and opportunities determined during planning, if necessary.
- Flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity.
- Take actions when timely and effective Corrective Actions are not achieved.

Documentation of the Nonconformity and Corrective Action process shall be maintained.

10.2.2 Documentation Required

When nonconformity occurs, we retain documentation as evidence of:

- The nature of the nonconformities and any subsequent actions taken.
- Results of any corrective action.

10.2.3 Continual Improvement

PMI shall continually improve the suitability, adequacy, and effectiveness of the QMS.

PMI shall consider the results of analysis and evaluation, and the outputs from Management Reviews, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

PMI shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.

NOTE: Continual improvement opportunities can include lessons learned, problem resolutions and the benchmarking of best practices.

Section 11: Revision History

Revision	Description	Date
AA	Updated the Quality Manual to current processes and added revision history.	4/7/2023