



# Quality Systems Manual

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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.

Prime Machine'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 Prime Machine Personnel. The manual also provides procedures and references for activities ensuring compliance to 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 Prime Machine is focused on Customer Satisfaction and Continuous Improvement.

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## **Quality Manual Distribution Policy**

Prime Machine'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.

Employee training records are kept for permanent employees of Prime Machine.

Access to this manual is provided to the Customer and/or Regulatory Agencies upon request or where appropriate to satisfy contractual obligation or compliance to our Customer's Internal Quality Systems.



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## Section 1: Scope

### *1.1 General*

This Quality Manual outlines the Policies, Procedures and Requirements of the Prime Machine Quality Management System (QMS). The system is structured to meet the intent of the conditions set forth in the International Standard ISO 9001:2015 and AS9100D.

Prime Machine is a multi-faceted service and production organization with a wide range of Customers. To assure all Customer needs are met, we have defined a system for determining the required levels of Documentation and Quality Control for each Customer Job. This Quality Control Level is identified by the Project Manager during the initial Contract Review and Work Order input.

We maintain three distinctly different Quality Control levels (see Section 4.3).

By defining the necessary level of Quality Control, we can provide cost competitive services to every level of Customer.



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## Section 2: Normative References

### *2.0 Quality Management System References*

The following document was used as reference during the preparation of the Quality Management System:

- ✓ SAE International Aerospace Standard AS9100:D



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## 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; drawings, work order routers, 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 Shop Management and Quality Personnel and may rework, repair, scrap or Use as is any component under their review. (See PMP-007 Nonconformance).
- ✓ **Network Job Folder** – This refers to the Directory created on the Prime Machine 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**-Prime Machine Flow Diagrams or Forms. These are also considered support documentation for this manual.
- ✓ **PMP**- Prime Machine Procedure. These are also considered support documentation for this manual.
- ✓ **PPC**-Prime Machine 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 Order Routers as required for additional process control.
- ✓ **Product** – The end item result of meeting all contract terms and conditions (manufactured goods, merchandise, services etc.)
- ✓ **QFM** - Prime Machine Quality Control Form
- ✓ **Quality Records** – Documentation of those activities where records must be maintained – this will be specified in the procedure or work instruction level documents, as applicable
- ✓ **Source Inspection**- An agreement made with the customer, government or their designee, to verify conformance of a product at Prime Machine or at Prime Machine Supplier’s premises



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- ✓ **Traveler-** The traveler 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, material certs 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** – The `Work in Process` status for the operations performed on a project.
- ✓ **Work Order Router-** 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 Router is considered the sole authority data for work in process and it is maintained within Global Shop with the most current sequence of operations. The Work Order Router is the initial planning step in the execution of a job, and as changes are made to work in process the Work Order Router shall be updated. (See PMP-003 Creation of Routers)

### **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 is able to perform to the designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

### **3.5 Special Requirements**

Those requirements identified by the customer, or determined by Prime Machine, which have high risks to being achieved, thus requiring their inclusion in the risk management process. Factors used in the determination of special requirements include product or



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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 Prime Machine's capacity, or requirements determined by Prime Machine 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. Formal Risk Analysis shall be performed on each QC Level III job at the time of Order acceptance.

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## **Section 4: Context of the Organization**

### ***4.1 Understanding the Organization and its Context***

Prime Machine, Inc. (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 Bldg.-Large CNC machinery and engineering services.

Because of the Customer diversity and the nature of the Services we offer, we believe that the work will never run out. Everything wears out or breaks eventually. There are many Competitors in this industry, and we have and strive to keep the good Reputation that keeps us competitive.

There are many challenges in dealing with these industries and providing the variety of Services that we do. Significant overtime is required from many of our Employees. Training Employees to use all of the Equipment and to understand the specialized Processes is expensive and time consuming. Low Unemployment Rates make it difficult to find and retain Qualified Employees and easy to lose Experienced and Knowledgeable Personnel. Competition does keep prices down except in cases of Emergency work. We normally only make small quantities of any parts.

### ***4.2 Needs and Expectations of Interested Parties***

All of our Customers are interested that we have a Quality Control System used in performing their work. Most, however, do not provide input or requirements that dictate how we run our Quality System.

1) Customers that work with us because of our AS9100D or ISO: 9001-2015 certifications require that we maintain that certification during the time 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 price they agreed to.

2) The Regulatory Body (ABS Group) certifying that Prime Machine conforms to AS9100D and ISO: 9001-2015 is interested in our Quality System and how it is implemented. ABS Group expects that we pass yearly Audits.

3) Prime Machine 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 Suppliers (Vendors) expect their Purchase Orders to be accurate. They also expect to be paid in a timely manner.



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5) Prime Machine Managers at all levels expect to follow an approved Management System to achieve results. They expect to have 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.

### ***4.3 Scope of the Quality Management System (QMS) – QUALITY LEVELS DEFINED***

Prime Machine, Inc. 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 Machine Shop, Weld Shop, 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:

575 West 800 South

Salt Lake City, UT 84101

TEL: 801-575-8430

Due to the large variety of work that is performed in the shop, we normally assign a "Quality Level" to each Job as the Project Manager enters it into our Global Shop system. This is done to alert each department performing the work as to the level of documentation and extent of inspection.

In practice, the Customer Purchase Order will normally define expected delivery, level of Quality Documentation and Inspection Reporting required. If it doesn't, our Project Managers must define these requirements.

- ✓ **Quality Level I-** Applies to work that is simplistic in nature and has minimal quality, inspection and documentation requirements. This work is initiated at the customer's discretion and communication of requirements and results can be verbal. Approval of quality and release of finished product or related activities can be made by the Prime Machine Area Manager or Production Manager.
- ✓ **Quality Level II-** Applies to work that has some complexity where Quality Planning is based upon best industry practices or Prime Machine workmanship standards and internal documentation. Specifications of Quality and Performance will be determined for each Job by the Project Manager. Prime Machine reserves the right to perform all Material Review activities on Quality level II projects.



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- ✓ **Quality Level III-** Applies to work where the Customer provides and/or specifies in writing or by contract, all specifications, drawings, applicable inspection plans and Quality Requirements. This information shall be provided before any related process is started. The Customer will be closely involved in all stages of planning, production, assembly, and inspection. The Customer will provide buy-off criteria and procedures or provide for source inspection of the work performed and shall reserve the right to conduct the Material Review activity.

#### ***4.4 Quality Management System and its Processes***

Prime Machine Inc. has established, documented and implemented a Quality Management System (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. Prime Machine's QMS will adhere to all Customer and applicable statutory and regulatory QMS requirements.

Documentation was developed to show the QMS Process Interactions (See QFM-244 QMS Process Interaction). This document defines the QMS Processes as: 1) Contract Review, 2) Production / Services, 3) Purchasing and 4) Management. The document discusses responsibility, Risks and Opportunities as well as Metrics used to assess the effectiveness of these Processes.

The Prime Machine QMS is composed of the following Main Documents:

QMS-001 Quality Manual

Prime Machine Procedures;

PMP-001 Document Control

PMP-002 Control of Records

PMP-003 Creation of Routers

PMP-004 Purchasing

PMP-005 Tool Management

PMP-006 Internal Audit

PMP-007 Non-Conformance

PMP-008 Inspection Report Control

PMP-009 Process Realization

PMP-010 Field Time Sheet Prep

PMP-011 Accident Reporting

PMP-012 Time & Payroll Rules

PMP-013 Accounts Payable

PMP-014 Employee Uniform Policy

PMP-015 Employee Hiring Policy



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### PMP-016 Documentation Retention & Destruction

There are other documents used (see QFM-205 Master Document Log), including:

PJPs – Job Descriptions

PMFs – Forms and Flow Charts

PPCs – Process Procedure Controls

QFMs – Quality Forms

Each document is Revision Controlled. Documents are to be reviewed to assure that they are relevant and up to date. This is the responsibility of the Quality Manager with the help of others as necessary.

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 Process is being carried out as planned.

#### **4.4.1 Quality Manual**

This Quality Manual has been prepared to describe the Prime Machine Quality Management System (QMS). The scope of the QMS is described in Section 1.



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Interactions between the AS9100 Specification,  
and Prime Machine Quality Documents

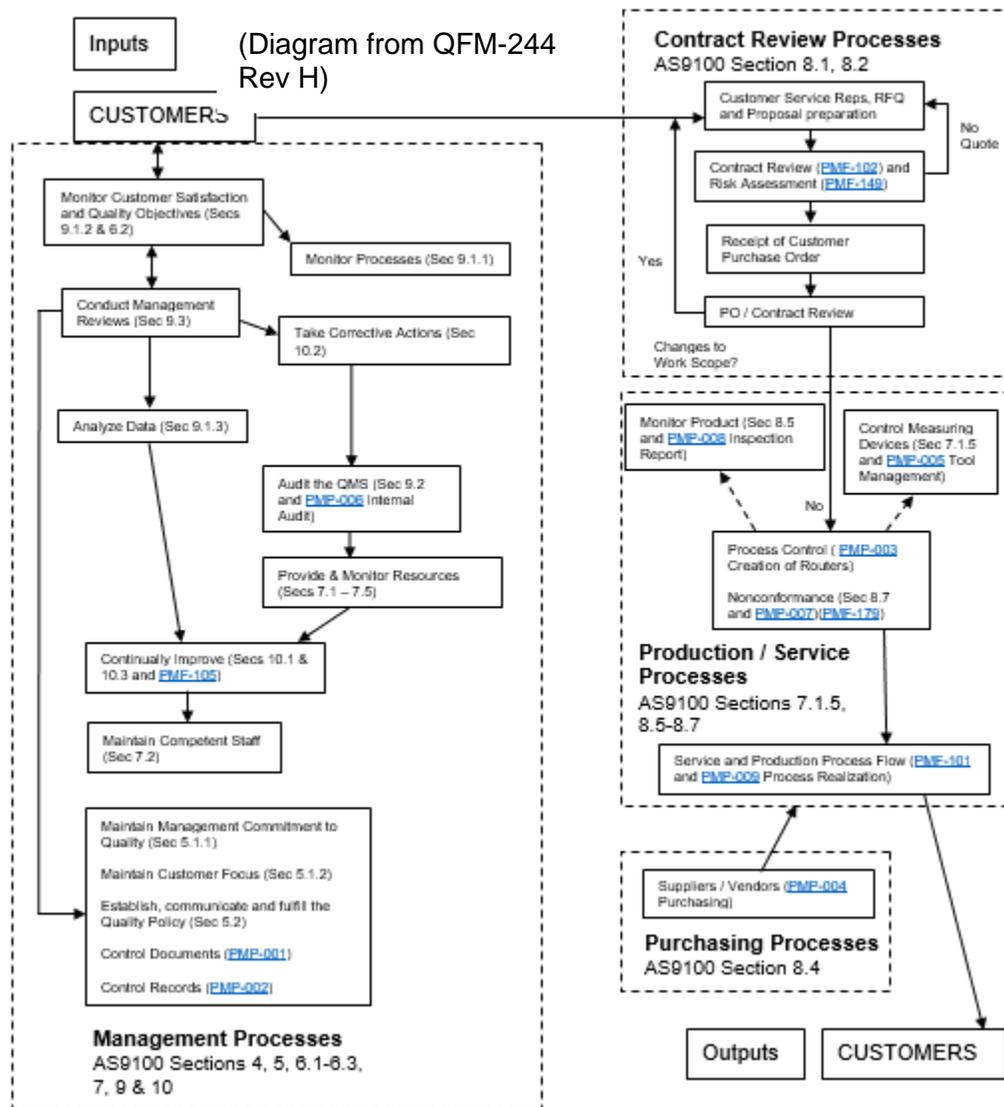


Figure 4.4.1 – QMS Process Interactions

### 4.4.2 Control of Documents

All of the QMS Documents are controlled according to Document Control Procedure PMP-001 as follows:

- ✓ Approving documents for adequacy prior to issue



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- ✓ 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 to apply suitable identification to them if they are retained for any purpose

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

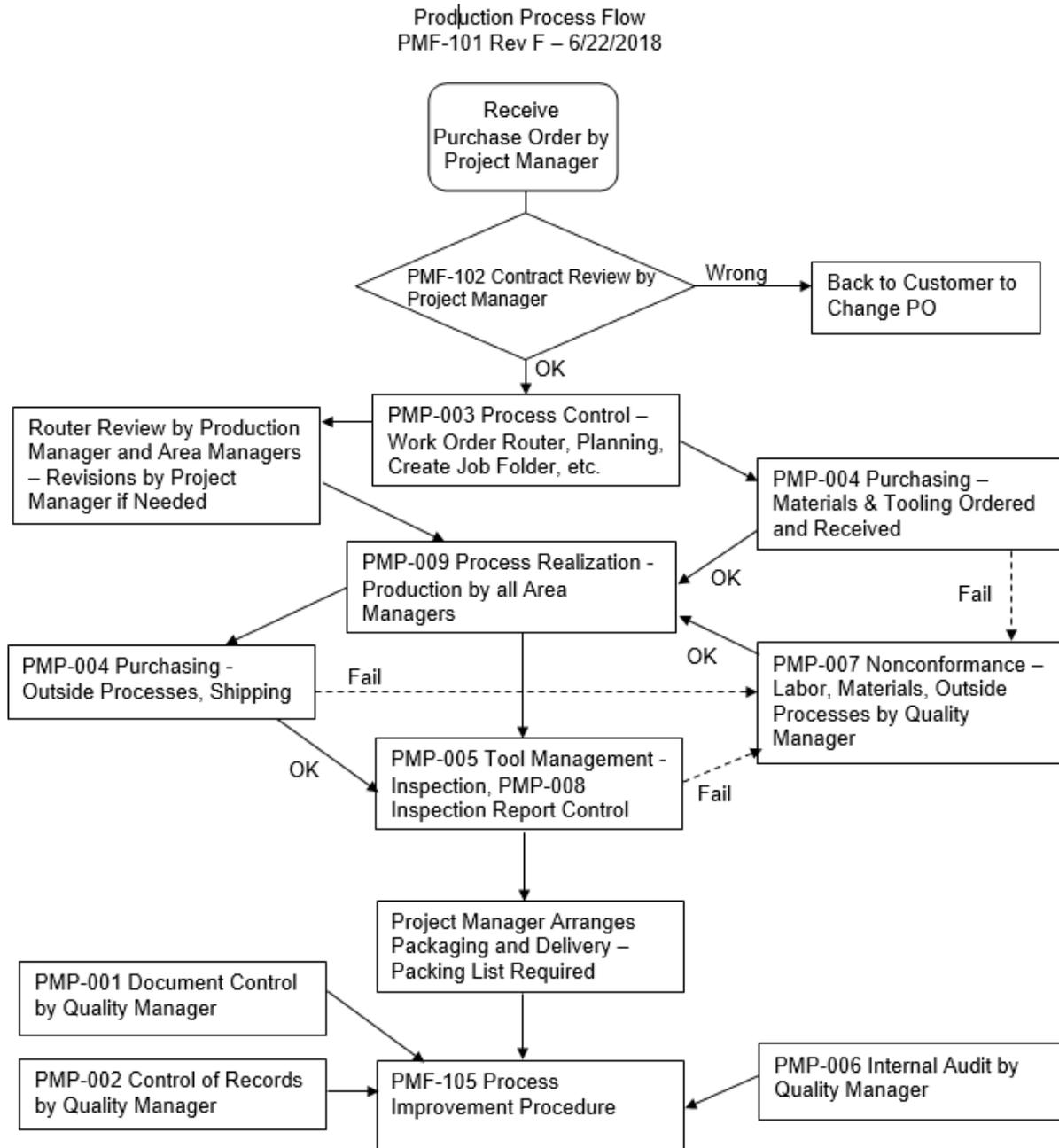
### ***4.4.3 Control of Quality Records***

Prime Machine Quality Records are maintained to provide evidence of conformity to QMS requirements. Quality Records are maintained according to PMP-002 Control of Records. 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 following Diagram shows the Process Interactions between the main documents making up the Prime Machine Quality Management System.



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**Figure 4.4.2 – Process Flow Diagram**

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## **Section 5: Leadership**

### ***5.1 Leadership and Commitment***

The Prime Machine management team is actively involved in implementing the Quality Management System (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***

Top management at Prime Machine includes: Chairman of the Board, President/Sales Manager, Operations 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***

Prime Machine strives to identify current and future customer needs, to meet Customer Requirements and exceed Customer Expectations.

Top 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.

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## 5.2 Quality Policy

**Prime Machine strives to be “First in business excellence, quality and value in the eyes of our Customers”.**

To support this Policy, we work to continually improve our People, Technology and Processes in the following manner:

- ✓ **People:** Prime Machine 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:** Prime Machine 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:** Prime Machine develops processes and procedures and then measures results to continually improve our Products and Services. Our Leadership commits to comply with our Quality Management System 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 Prime Machine
- ✓ 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 communicating the Quality Policy within Prime Machine. These include; weekly Staff Meetings and regular Management Reviews.

The Quality Policy shall:

- ✓ Be available and maintained as Documented Information
- ✓ Be communicated, understood and applied within Prime Machine
- ✓ Be available to relevant interested parties, as appropriate



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## 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 Prime Machine. Job functions and the organizational chart are reviewed and approved by Top Management for adequacy. This chart is available in this Quality Manual to help employees understand lines of authority within the Organization.

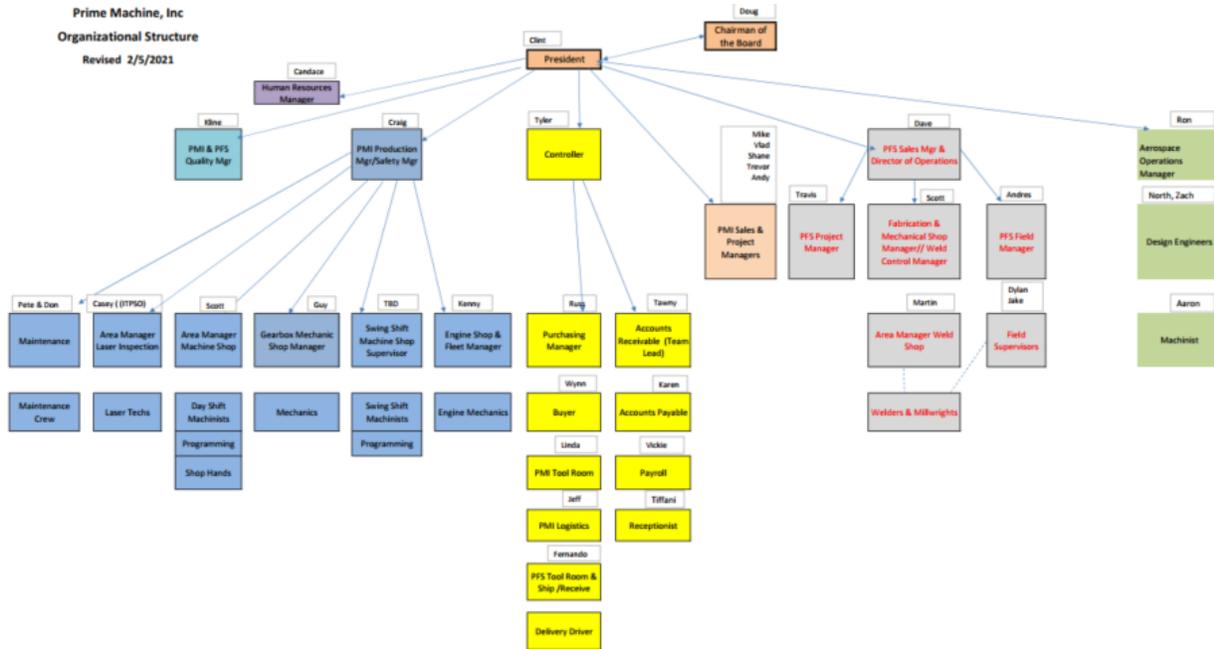


Figure 5.3.1 – Prime Machine Organization Chart

### 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 Quality Management System conforms to the requirements of the International Standards for AS9100 and ISO-9001
- ✓ Ensure that the work processes are delivering their intended outputs



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- ✓ Report to Top Management on the performance of the QMS and note opportunities for improvement
- ✓ Promote awareness of Customer Requirements throughout Prime Machine
- ✓ 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 Prime Machine. This includes; defining the extent of the Program, maintaining compliance to all procedures, and improving the Program based on Customer needs
- ✓ In charge of Quality Management System Records Retention
- ✓ Product Warranties
- ✓ Root Cause Analysis and associated Corrective Actions
- ✓ Continuous Improvement throughout the company

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## **Section 6: Planning**

### ***6.1 Actions to Address Risks and Opportunities***

#### ***6.1.1 Determine Risks and Opportunities***

We need to determine the Risks and Opportunities that need to be addressed 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***

We need to plan for the following actions regarding Risks and Opportunities:

- ✓ Integrate and implement the actions into our QMS
- ✓ Evaluate the effectiveness of these actions.

Options to address Risks can include; avoiding risk, taking risk to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk or retaining risk by informed decision.

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 Prime Machine's or its Customer's needs.

Documentation was developed to show the QMS Process Interactions (See QFM-244 QMS Process Interaction). This document defines the QMS Processes as: 1) Contract Review, 2) Production / Services, 3) Purchasing and 4) Management. The document 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 –



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We strive for **100% Customer Satisfaction** and measure this by a combination of Surveys and input from our Salesmen 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. This will only be tracked for Quality Level 3 jobs.

✓ Product Quality –

We think we can reach a level of 70% of Jobs without nonconformance. Based on written NCRs, we will determine Product Quality for Quality Level 3 Jobs only.

✓ Safety –

A safe work environment is required to provide quality work. Our goal is to maintain an average EMOD less than 1.0 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 Prime Machine during the year.)

These Quality Objectives are consistent with the Quality Policy, measurable, monitored and discussed at Management Review Meetings.

The Quality Manager shall maintain 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 Prime Machine 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;



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- ✓ Who will be responsible;
- ✓ When it will be completed;
- ✓ How the results will be evaluated.

### ***6.3 Planning of Changes***

When Prime Machine determines the need for changes to the Quality Management System, the changes shall be carried out in a planned manner, considering the following:

- ✓ Purpose of the Changes and their potential consequences;
- ✓ Integrity of the Quality Management System;
- ✓ Availability of Resources;
- ✓ Allocation or reallocation of Responsibilities and Authorities.

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## **Section 7: Support**

### ***7.1 Resources***

#### ***7.1.1 General***

Prime Machine has implemented a QMS that complies with AS9100D and ISO-9001:2015 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 a copy of the Quality System documentation. 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 on 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 (see PMF-151 Training Acknowledgement Form).

#### ***7.1.3 Infrastructure***

To meet Quality Objectives and Product Requirements, Prime Machine 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 or regular Staff Meetings. Existing infrastructure is maintained as required (see QFM-501 Maintenance Repair Form).

#### ***7.1.4 Work Environment***

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



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Data from the Quality System is evaluated to determine if the Work Environment is adequate to achieve Product Conformance or if Preventive or 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***

Prime Machine 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 Creation of Routers).

Prime Machine ensures that resources provided are:

- ✓ Suitable for the specific type of monitoring and measurement activities being undertaken, and
- ✓ 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***

Prime Machine Quality Manager will determine the required monitoring and measurements to be undertaken during the manufacture of each component specified in the Work Order Router.

Prime Machine maintains a register of standard monitoring and measuring devices and has defined the process employed for their calibration and use (see PPC-556 Calibration Program). 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.

Prime Machine 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:



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- ✓ Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded.
- ✓ 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
- ✓ Prime Machine 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, Prime Machine takes appropriate action on the equipment and any product thought to be affected.

### ***7.1.6 Organizational Knowledge***

Prime Machine 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, vendors etc.

### ***7.2 Competence***

Prime Machine Top Management shall:

- ✓ Determine the necessary competence of Workers that affect the performance and effectiveness of the Quality Management System
- ✓ 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



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- ✓ 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 Quality Management System, 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**

Prime Machine Quality Manager shall determine the internal and external communications relevant to the Quality Management System 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**

Prime Machine's QMS shall include:

- ✓ Documented information required by AS9100D Standard
- ✓ Documented information determined by Prime Machine to be necessary for QMS effectiveness.



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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 Master Document Log. Control of documents follows standards in PMP-001 Document Control.

### **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, Prime Machine shall address the following activities as applicable:

- ✓ Distribution, access, retrieval and use (see PMP-002 Control of Records),
- ✓ 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.



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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.)



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### Section 8: Operation

#### *8.1 Operational Planning and Control*

Prime Machine 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 Vendors and ensure that outsourced process are controlled as necessary;
- ✓ Establish controls to prevent the delivery of nonconforming Products and Services to the Customer;
- ✓ Configuration Management appropriate to the product;



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- ✓ 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 Creation of Routers.

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 Router.

### ***8.1.1 Operational Risk Management***

Prime Machine Management shall plan, implement and control a process for managing Operational Risks (see PMP-009 Process Realization) 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 Risks & Opportunity Analysis). 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 Risk Analysis). It is expected that this form be used before each job as an aid in assessing risk.

### ***8.1.2 Configuration Management***

Prime Machine 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 Inspection Report Control and QFM-209 Inspection Report Form). This process shall:



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- ✓ Control Product Identity and Traceability, including the implementation of identified changes, and;
- ✓ 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**

Prime Machine 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**

Prime Machine Management shall plan, implement and control processes appropriate to the Product for the prevention of counterfeit or suspected counterfeit part use and their inclusion in products delivered to the customer (see PMP-004). Counterfeit part prevention should consider:

- ✓ Controls for acquiring externally provided product 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 deal with.

## **8.2 Requirements for Products and Services**

### **8.2.1 Customer Communication**

Prime Machine Project Managers are always in close contact with our Customers. As an order progresses thru 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



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- ✓ 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***

Prime Machine Project Managers determines Customer Requirements before acceptance of an order. Product or Service Requirements may include:

- ✓ Statutory and regulatory requirements related to the product
- ✓ Those requirements considered necessary by Prime Machine
- ✓ Those requirements requested by the customer
- ✓ Customer specifications or other standards
- ✓ Any special requirements

### ***8.2.3 Review of Requirements for Products and Services***

Prime Machine Sales Manager has a process in place for the review of requirements related to the product and services we provide (see Contract Review PMF-102).

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

- ✓ Customer requirements are reviewed.
- ✓ Statutory and Regulatory requirements are identified and planned for
- ✓ Contract or order requirements differing from those previously expressed are resolved
- ✓ Prime Machine has the ability to 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.



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### **8.2.4 Changes to Requirements for Products and Services**

When product requirements are changed, Prime Machine 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 resource in a work order which is input to Global Shop.
- ✓ 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.



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### ***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 managements approval to move forward the job is initiated, and a project manager will be assigned, and the job will be entered into Global Shop and begin to be planned. Global Shop 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 Global Shop. 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 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



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- 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 in the Global Shop 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,



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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 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 Engineering Change Notices (ECNs).
- ✓ Our Company 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.



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We are required to retain the 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.
  - Engineer evaluates for feasibility and design impact
  - Project manager evaluates for scope and cost impact
- ✓ The change request will be reviewed by 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 Vendor Processes, Products and Services***

#### ***8.4.1 Purchasing Process***

A documented Control Procedure for Purchasing (see PMP-004 Purchasing) is followed to ensure that purchased product conforms to the specified requirements. The procedure outlines the extent of control required for Vendors and the purchased product or service. Prime Machine is responsible for the Quality of Products purchased from all Vendors, including customer-designated sources.

Vendors 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. Prime Machine Purchasing Manager will do the following:

- ✓ Maintain a register of approved suppliers that includes the approval status (approved, conditional, disapproved) and the scope of the approval (product type or process family)
- ✓ Require that Vendors apply appropriate controls to their direct and sub-tier external providers to ensure that requirements are met
- ✓ Periodically review supplier performance (including process, product and service conformity, and on-time delivery performance) and retain documented



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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 suppliers that do not meet requirements (see PMP-007)
- ✓ Ensure where required that both Prime Machine and all Vendors 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 suppliers depending on the supplier's approval status.
- ✓ Determine and manage the risk when selecting and using suppliers.
- ✓ Define requirements for controlling documentation created by and/or retained by our Vendors.

NOTE: One factor that can be used during supplier 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 Purchasing describes the processes used to verify that purchased product meets specified requirements. Prime Machine Purchasing Manager will do the following:

- ✓ Ensure that externally provided processes remain within our QMS.
- ✓ Define controls applied to Vendors and to output from those Vendors.
- ✓ Consider the impact of Vendor products or services on meeting our Customer's requirements.
- ✓ Consider the effectiveness of Controls applied by our Vendors.
- ✓ Determine the verification necessary to ensure Vendor 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 Vendors (accompanying documentation, certificate of conformity, test reports, statistical records and process control).
- ✓ Audit our Vendors (see QFM-202 Supplier Questionnaire) and review the results. Inspect Vendor premises as deemed necessary by the Purchasing Manager.
- ✓ Inspect products from Vendors upon receipt per Project Manager request (see PMP-004 for details).



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- ✓ Review any required Product Verifications delegated to our Vendors.

When 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 Prime Machine of its responsibility to provide acceptable product and comply with requirements.

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

If Prime Machine delegates verification activities to a Vendor, the requirements for delegation are defined and a register of delegations shall be maintained.



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### **8.4.3 Information provided to Vendors**

Purchasing Documents are to be reviewed to ensure the adequacy of requirements before orders are placed with a Supplier.

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 Vendor interactions with Prime Machine
- ✓ Any special Vendor controls or monitoring required by Prime Machine
- ✓ Any verification or validation that Prime Machine or its Customer may need to perform at the Vendor'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 Prime Machine
- ✓ The need to implement a Quality Management System
- ✓ The need to use approved external providers (if necessary)
- ✓ Requirements to notify Prime Machine of nonconforming product, obtain Prime Machine approval for nonconforming product, notify Prime Machine of changes in product and/or process, changes of suppliers, changes of manufacturing facility location and, where required, obtain Prime Machine 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 Prime Machine, its customer, and regulatory authorities to all facilities involved in the order and to all applicable records
- ✓ Reminder to the Vendor 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***

Prime Machine 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, Travelers, 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 in the sequence verification operations are to be performed
  - 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 persons, 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 product 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.)



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- ✓ 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 and,
- ✓ 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, Prime Machine 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.



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### ***8.5.1.3 Production Process Verification***

Prime Machine 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 are capable of producing 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***

Prime Machine identifies the product throughout product realization in accordance with PMP-003 Process Control. The Work Order Router is the primary document for identifying all identification requirements and capturing all traceability needs.

Prime Machine maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the required configuration.

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

Prime Machine 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 Router.

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

According to the level of traceability required by contract, regulatory or established requirement, Prime Machine'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.
- ✓ For an assembly, the identity of its components and those of the next higher assembly to be traced.
- ✓ For a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.

### ***8.5.3 Customer or Vendor Property***

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



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Control of Customer property is outlined in the following procedures: PMP -005 Tool Management and PMP-007 Nonconformance.

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**

Prime Machine 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

Prime Machine 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**

Prime Machine 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**



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products. If we do Reverse Engineering of Customer components, we do need to 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 do send out a Customer Satisfaction questionnaire (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 Prime Machine 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 field work is completed by our Sister Company – Prime Field Service, which is not an AS9100-certified company.
- ✓ Product / Customer Support (queries, training, warranties, maintenance, replacement parts, resources, obsolescence, etc.): We do provide a Warranty (QFM-235 Prime Machine Seller Warranty) 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, Prime Machine 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 Globalshop 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-



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mail is to be stored in the Network Job Folder along with any other pertinent information provided.

Since all products made by Prime Machine 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 under direction of the Company President. Project Manager needs to work closely with the Quality Manager to make sure warranted 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***

Prime Machine shall review and control changes for production or services, to the extent necessary to ensure continuing conformity with requirements (see PMP-003 Creation of Routers).

Persons authorized to approve changes to production shall be identified.

Prime Machine 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***

Prime Machine 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 Shipping Authorization).

Prime Machine 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

Prime Machine 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***

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### 8.7.1 Identification of Nonconforming Outputs

Prime Machine 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 Nonconformance.

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

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

Prime Machine 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 taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started
- ✓ Prime Machine’s nonconforming product control process provides for timely reporting of delivered non-conforming product: Note: Parties requiring notification of nonconforming product can include suppliers, internal organizations, customers, distributors and regulatory agencies.
- ✓ By taking actions necessary to contain the effect of the nonconformity on other processes or products.

Prime Machine 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.

Prime Machine 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.



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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 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**

Prime Machine shall retain documented information that:

- ✓ Describes the Nonconformity
- ✓ Describes the Actions taken
- ✓ Describes any Concessions obtained
- ✓ Identifies the authority deciding the action in respect to the nonconformity
- ✓ Is located in the Global Shop Quality Module

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## **Section 9: Performance Evaluation**

### ***9.1 Monitoring, Measurement, Analysis and Evaluation***

#### ***9.1.1 General***

Prime Machine 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.

Prime Machine shall evaluate the performance and effectiveness of the QMS.

Prime Machine shall retain appropriate Documented Information as evidence of the results.

#### ***9.1.2 Customer Satisfaction***

Prime Machine Sales Manager shall monitor information relating to Customer perception as to whether Prime Machine 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, Prime Machine Salesmen feedback, compliments, warranty claims and dealer reports. We do have a standardized email survey to be used for Customer feedback.

Prime Machine shall develop and implement plans for Customer satisfaction improvement that addresses 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



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- ✓ Performance and effectiveness of the QMS
- ✓ Whether planning has been implemented effectively
- ✓ Effectiveness of actions taken to address Risks and Opportunities
- ✓ Performance of Vendors
- ✓ Need for Improvements to the QMS

### ***9.2 Internal Audit***

#### ***9.2.1 Audit Intervals***

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

- ✓ Conforms to Prime Machine'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 Internal Audit). 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 Internal Audit Schedule)
- ✓ 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.



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### ***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 Quality Management System at planned intervals to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the Organization (see PMF-127 Management Review Agenda)

#### ***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 Measurement Results
- ✓ Status of Preventive and Corrective Actions
- ✓ Results of Audits
- ✓ Scrap and Rework Costs
- ✓ Performance of Vendors
- ✓ 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:



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- ✓ 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.



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### **Section 10: Improvement**

#### ***10.1 General***

Prime Machine 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; Correction, Corrective Action, Continual Improvement, Breakthrough Change, Innovation and Re-organization.

#### ***10.2 Nonconformity and Corrective Action***

Prime Machine takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered (see QFM-201 NCR Form).

##### ***10.2.1 Nonconformity Actions Required***

When nonconformity occurs, the Organization 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 a Vendor, when it is determined that the Vendor is responsible for the Nonconformity,



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- ✓ 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 shall retain Documentation as evidence of:

- ✓ Nature of the Nonconformities and any subsequent Actions taken
- ✓ Results of any Corrective Action

### **10.2.3 Continual Improvement**

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

Prime Machine 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.

Prime Machine 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.