



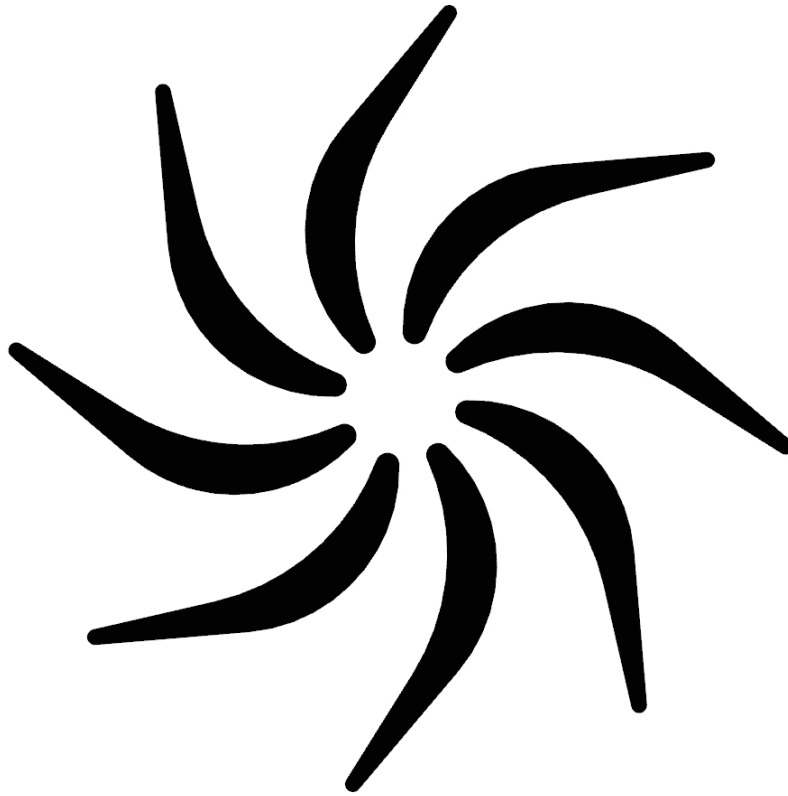
AS9100C Quality Systems Manual

Pacific Pattern Technologies, LLC
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CEO/Quality Manager: Gregg B. Turner

Signed: _____ *Gregg B. Turner* _____ Dated _____

06-23-2017



Quality is the center of our engine
Standardization is in our vanes
Acceleration is our performance
Precision is what we deliver!

Our Team has committed to the constant improvement of producing quality products through our inherent integration of quality systems, standardization and manufacturing processes. We improve technologies to reduce costs, lead times while improving product quality.

Introduction

The Quality Management System of **Pacific Pattern Technologies** meets the requirements of the international standard SAE AS9100C. This system addresses the design, development and production of the company's products.

The manual is divided into eight sections that correlate to the Quality Management System sections of the ISO 9001:2008 format and AS9100C. Each section begins with a policy statement expressing **Pacific Pattern Technologies'** obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the AS9100 Rev C standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our 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 Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

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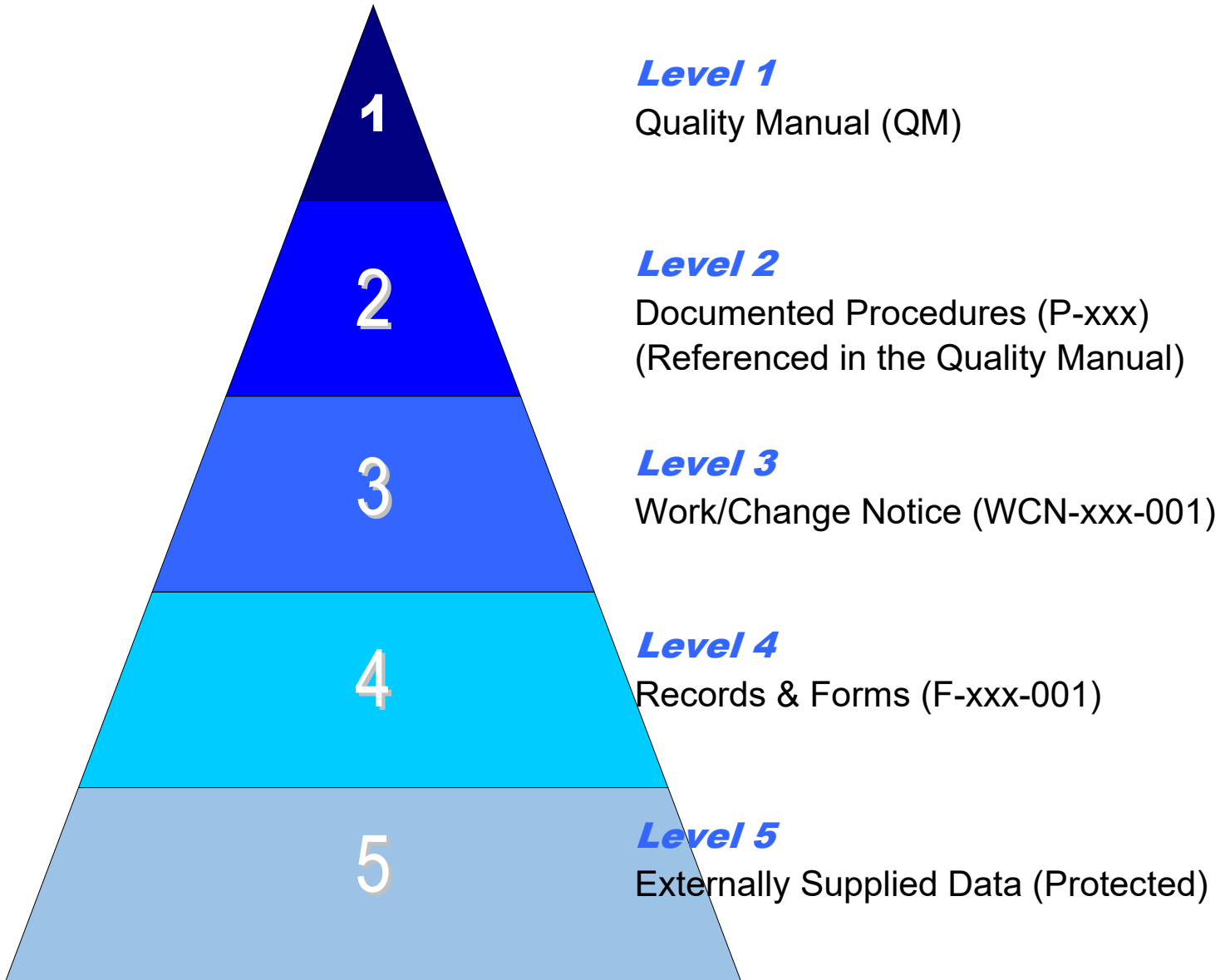
Organization Chart



“Quality is the center of our engine”

Figure 1

Quality Management System



Quality Manual Distribution

The Quality Manual is distributed electronically to all Project Managers

Section 1: Scope

1.1 General

This quality manual outlines Pacific Pattern Technologies quality management policies, organization and documentation structure, and defines management responsibility for the Quality Management System processes.

The system is structured to comply with the conditions set forth in the International Standard SAE AS 9100 Rev C.

Pacific Pattern Quality Management System includes all activities affecting product quality and customer satisfaction (except processes listed below), beginning with the assessment and definition of new customer orders, including all planning and product realization activities, and ending with the delivery of conforming product.

1.2 Application

Pacific Pattern Technologies has determined that the following requirements are not applicable to the operations at this site at this time and are documented as exclusions:

- Configuration Management P-713
- Statistical Techniques P-840

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1.3 Company Overview

Pacific Pattern Technologies is an organization specializing in design and manufacturing of tooling for investment cast foundries.

Pacific Pattern Technologies is committed to satisfying the needs of our customers. We produce only quality product and deliver our products and services on time. We gladly accommodate short delivery times to meet our customers' needs.

Pacific Pattern is committed to a policy of continuous improvement of our products, processes and our systems.

Pacific Pattern operates at one location;
1445 NE Miller St. Ste A5 McMinnville Or 97128

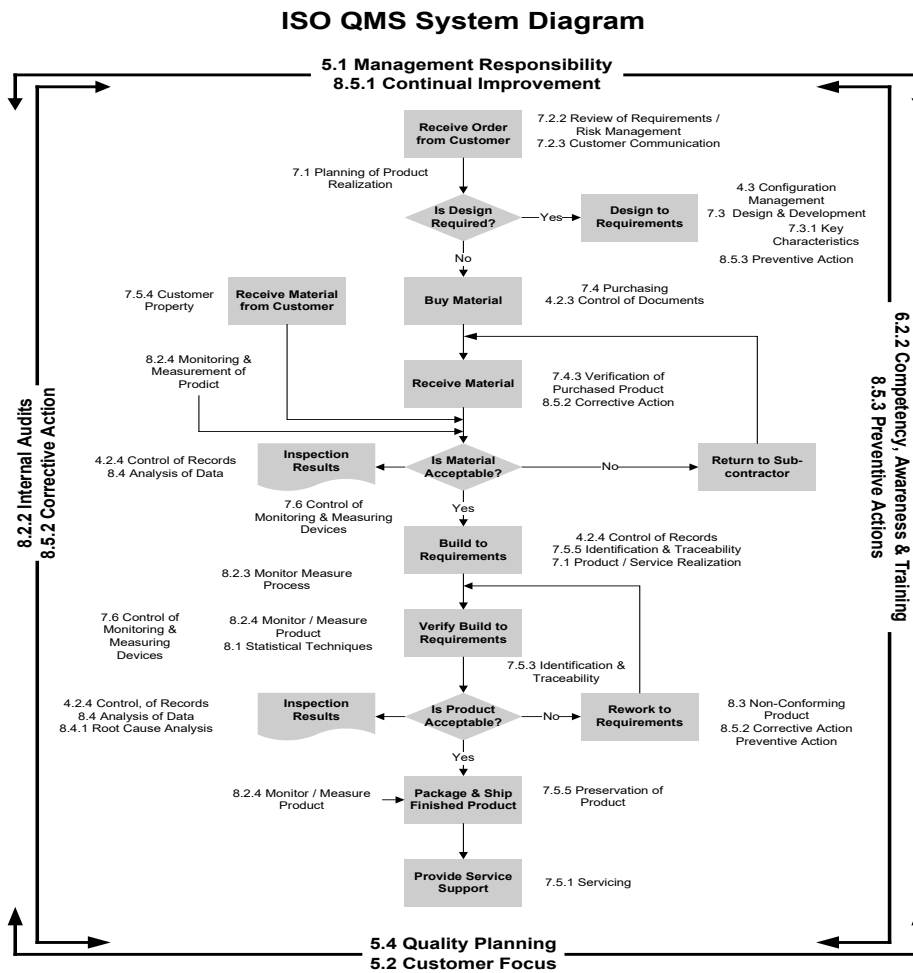
The CEO has the overall responsibility for all operations.

1.4 Quality Management System

The following diagram represents the processes that make up the key functions of the Quality Management System (QMS).

QUALITY MANAGEMENT SYSTEM (QMS) PROCESS FLOW CHART

This Diagram is an example only!



Section 2: Normative Reference

2.0 Quality Management System References

The following documents were used as reference during the preparation of the Quality Management System:

- ISO 9000:2005, Quality Management Systems - Vocabulary.
- ISO 9001:2008, Quality Management Systems – Requirements
- ISO 9004:2009, Quality Management Systems – Guidelines for Performance Improvements
- SAE AS9100 Rev C (2009) - Quality Management Systems – Requirements for Aviation, Space and Defense Organizations

Section 3: Definitions

3.0 Quality Management System Definitions

- 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.
- Product – The end item result of meeting all contract terms and conditions. (eg: manufactured goods, merchandise, services etc.)
- Quality Records – Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable
- Key Characteristics- The features of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or manufacturability.
- Risk - An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.
- Special requirements - Those requirements identified by the customer, or determined by the organization, 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 process complexity, past experience and product or process maturity.
- Critical items - Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product; including safety, performance, form, fit, function, produce ability, service life, etc.; that require specific actions to ensure they are adequately managed.

Section 4

Quality Management System

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4.1 General requirements

Pacific Pattern Technologies has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of AS9100C and statutory and regulatory requirements. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

To design and implement the QMS Pacific Pattern Technologies has:

- Determined the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the Quality Manual
- Determined the sequence and interaction of these processes, and illustrated them on the Process Flow Diagram
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective.
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes.
- Established systems to monitor, measure and analyze these processes
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes.
- Defined the controls for outsourced processes.

4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

- Documented statements for the Quality Policy and Quality Objectives
- This Quality Manual
- Documented Procedures
- Documents identified as needed for the effective planning, operation and control of our processes, and
- Quality Records
- Records required by statutory and regulatory authorities.

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Pacific Pattern Technologies ensures that personnel have access to quality management system documentation and are aware of relevant procedures and changes. We also provide customer or statutory and regulatory authority's access to quality management system documentation.

4.2.2 Quality manual

The scope and permissible exclusions of the QMS are described in section one of this manual. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section. The Process Flow Diagram at the end of section 4 provides a description of the interaction between the processes of the QMS system. The relationship between the AS9100C standard and documented procedure has been indicated by use of a numbering system that correlates to the AS9100 standard.

4.2.3 QMS Document Control

All of the QMS documents are electronic and controlled according to the Document Control Procedure (QSP-423).

- Creating Quality System Procedures (QSP)
- Creating Quality System Forms (QSF)
- Creating Form Sections
- Approving QMS documents for adequacy prior to issue
- Document identification
- Document Distribution
- Reviewing, revising and re-approving documents

4.2.4 External Document and DPD Control

All externally received DPD is controlled per (QSP-424) Control of External Data. The procedure defines the process for:

- Induction of data to facilities
- Determination of use and purchase order acceptability
- Confirming proper DPD for production
- Storage and life term of documents and data
- Control of revisions
- Control of externally distributed DPD
- Backup of all documents and DPD

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4.2.5 Control of Quality Records

Quality records are maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. The records, including those created by or maintained by suppliers, are maintained according to the Control of Quality Records Procedure (QSP-425). Quality records are retained for 10 years.

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.

Related Procedures

Control of QMS Documents	QSP-423
Control of External Documents and DPD	QSP-424
Control of Quality Records	QSP-425

Section 5

Management Responsibility

5.1 Management commitment

The CEO is responsible for implementing the quality management system (QMS). The CEO has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

To continue to provide leadership and show commitment to the improvement of the QMS, the CEO will do the following.

- Communicate the importance of meeting customer, statutory, and regulatory requirements,
- Establish quality objectives,
- Establish the quality policies,
- Conduct annual management reviews,
- Ensure the availability of resources,
- Implement our Quality Policy.

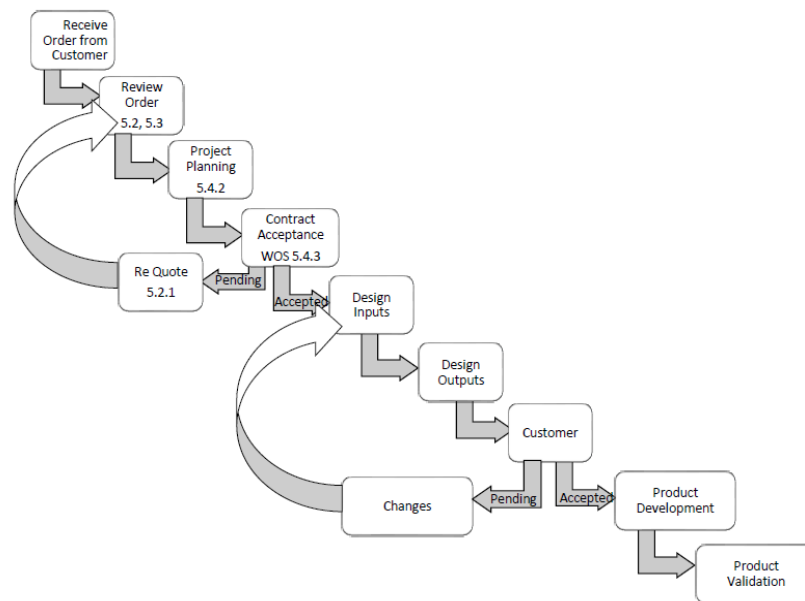
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5.2 Customer focus

The CEO and Project Managers have created (QSP-720) to convey to our customers the procedures used to control communication, planning, quality and product development. This procedure demands that we:

- Strive continually to improve customer needs and communications.
- Complete contract review and resolves issues within 48 hours of contract receipt,
- Develop product with traceable controls,
- Communicate clearly and timely through the key stages of product planning, design and realization.
- Identifies, documents, and implements current and future customer needs.



We have developed a Work/Change Order Notification system that ensures PPT management communicates effectively internally and externally with each customer throughout planning, design and development stages to ensure no issues go undetected and are communicated clearly.

The CEO ensures that all discrepancies, delays and/or changes are communicated to the customer within 48 hours upon recognition for swift resolution.

The CEO ensures that product conformity, customer satisfaction and on-time delivery performance are measured and that appropriate action is taken to resolve future issues.

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5.3 Quality Statement and Policy

The CEO ensures that the quality policy is communicated to all employees. It is included in new employee training and training on the QMS. It is posted in prominent places throughout the facility to maintain high standards within our organization.

The CEO reviews the quality policy at each management review meeting to determine the policy's continuing suitability for our organization. The Quality Policy is documented on [\(A-500-001, Quality Policy\)](#).

5.4 Quality Planning

5.4.1 Quality Objectives

The quality system has been designed and implemented to meet our quality objectives and the requirements of the AS9100 standard.

Due to the inheritance of our quality system throughout all of our processes our quality objectives are continually changing to allow seamless integration within each process.

Quality Management System (QMS) objectives are reviewed continually for sustainability and effectiveness by the CEO.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

An organizational chart has been established to show the interrelation of personnel in the organization. Job descriptions, responsibilities and authorities are defined and distributed to each member and stored within the Human Resource system. Job descriptions and the organizational chart are reviewed and approved by the CEO for adequacy. The organization chart is located on page 4 of this manual.

5.5.2 Management representative

The CEO is the management representative. As management representative, the CEO has the following responsibility and authority:

- Ensure that processes needed for the quality management system are established and implemented.
- Ensure that personnel report to the CEO on the performance of the quality management system, and note needed improvements.
- Promote awareness of customer requirements throughout the organization.

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- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS.
- Resolve matters pertaining to quality issues.
- Organizational freedom and unrestricted access to resolve matters pertaining to quality.

5.5.3 Internal communication

Pacific Pattern Technologies (PPT) has adopted one form of internal communication to control all processes, engineering changes, quality changes and manufacturing. The process established for communication within the organization is done electronically utilizing the Work/Change Notification System (WCN) which is explained in detail in (QSP-711).

The CEO is responsible to initiate the WCN for all internal and externally supplied new projects or changes to projects, processes or procedures.

Each WCN is assigned a "Project Manager", the Project Manager is responsible for completeness and execution of each process defined on the WCN. The WCN will include key characteristics, process concerns, process improvements, process validation, process completion, process time, quantities.

Meetings are used throughout the week to review that production schedules are being met and to review the status of all WCN's in process.

Upon completion of a WCN, a meeting is conducted for closure

5.6 Management review

5.6.1 General

The CEO reviews the QMS system randomly by initiating internal audits of each procedure to ensure each procedure is recorded and meeting the requirements and responsibilities set forth by this QMS. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes. These audits are initiated and documented utilizing a WCN.

5.6.2 Review input

Assessment of the QMS is based on a review of information inputs from internal audits. These inputs include the following:

- Results and completeness of the WCN system
- Customer feedback
- Status of preventive and corrective actions (documented on the WCN)
- Planned changes that could affect the quality management system

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- Items needing retraining and improvement.

5.6.3 Review output

During these review meetings, the CEO will identify appropriate actions to be taken regarding the following issues:

- Improvement of the effectiveness of the quality management system and its policies
- Improvement of product related to customer requirements
- Resource needs

The CEO accepts the responsibility for required actions and may assign such actions to a Project Manager utilizing a WCN. Any decisions made during the meeting, assigned actions, and their due dates are recorded on the WCN.

Section 6

Resource Management

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6.1 Provision of resources

Pacific Pattern Technologies has implemented a Quality Management System that complies with the AS9100C standard. This implementation was achieved with management commitment and with sufficient resources for the implementation. To enhance customer satisfaction and effectively maintain and continually improve the system, management determines and provides necessary resources primarily driven through the CEO.

6.2 Human resources

To ensure competence of our personnel, job descriptions have been prepared identifying the qualifications required for each position that affects product quality. Qualifications include requirements for education, skills and experience, appropriate qualifications, along with required training, provide the competence required for each position. The job descriptions are not maintained as control documents and are under the management of the CEO and found under the system directory N: Administration/Human Resources/Job Descriptions.

6.2.1 Competence, awareness and training

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. The CEO maintains records of employee progress. The CEO is responsible to train each employee to a level necessary competence each project. Employees are trained on each procedure and CEO approval is documented in the Training table in paragraph 10.0 of each procedure.

All employees are trained by the CEO and/or General Manager on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

6.3 Infrastructure

To meet quality objectives and product requirements Pacific Pattern Technologies has determined the infrastructure needed (QSP-630). The infrastructure has been provided, and includes one (1) 2000 sq. foot building, work areas, utilities, process equipment and supporting services. As new infrastructure requirements arise, they will be documented as a new project utilizing the WCN. Existing infrastructure is maintained daily to ensure product conformity. Infrastructure maintenance requirements are not documented.

6.4 Work Environment

A work environment designed specifically for achieving product conformance and operator effectiveness is defined and maintained. The work environment is managed for continuing suitability. Each work center is evaluated to determine if the work environment is effective for achieving product conformance, or if preventive or corrective action related to the work environment is required.

6.4.1 Work Center Environments

Each work center is design for optimum user performance and to allow the ease of user substitution. All tools are consistent between centers and have a designated place that is to be maintained throughout production.

Section 7

Product Realization

7.1 Planning for product realization

Planning for production as well as monitoring production and controlling is controlled by the use of the (WCN Work/Change Notification System) in accordance with (QSP-711).

7.1.1 Work/Change Notification System

Project and quality planning procedures are executed upon the receipt of a new purchase order, customer property, customer changes, quality or process changes.

The process used to review, evaluate and record the plan is called the **Work Change Notification System** (WCN) which is explained in detail (QSP-711).

The WCN includes Quality Planning, Contract Review, Design Planning, Customer Review and Acceptance, Material Control, Manufacturing, and Validation Planning. The WCN also retains all of the records for each project within its electronic shell.

7.1.2 Project Management

Project planning includes assignment of a project manager, documented manufacturing plans, processes, procedures, design outputs and customer communication forms.

The CEO assigns responsibility for project management and ensuring that product realization is planned and managed in a controlled manner, meeting requirements at acceptable risk, within resource and schedule constraints.

Using the WCN the CEO identifies, reviews and records:

- Project Manager
- Risks, quality objectives, key characteristics and requirements for the product order,
- Processes, production documentation and resources required,
- Verification, validation, monitoring, measuring, inspection and test requirements,
- Customer focus and satisfaction.

The Project Manager is responsible to:

- Verify all Purchase Order requirements and electronic entries by the CEO on the WCN,
- Verify and approve the quotation requirements and commitments,
- Verify that all key characteristics, design inputs have all been incorporated into the design plan,

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- Verify that all Design Outputs have been completed and distributed accordingly...

These items are all initialed when approved and recorded in the WCN system (QSP 7.1.1).

7.1.3 Risk Management

Risks are managed according to the Risk Management procedure (QSP-713). The process of risk management includes;

- Assigning responsibility for risk management
- Defining risk criteria
- Identification, assessment and communication of risks
- Identification, implementation and management of actions to minimize risks

7.1.4 Project Plan

Projects are planned and outlined into key stages of production using the Work Instruction within the WCN system. These stages are used to update customers and personnel on the status of each stage via a milestone graph in accordance with (QSP 711) Work Change Notification System.

7.1.5 Customer Interaction

Customer satisfaction is our number one goal and concern. We have implemented steps to monitor and ensure satisfaction defined in detail in (QSP-720) Customer Focus.

The WCN system is designed for complete interaction with our customers throughout their project. Our customers are updated with the following:

- PO acceptance
- PO and Delivery Status
- Schedule and Delays
- Design Review
- Design Approval
- Progress
- Verification, FAI and CMM Results

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7.1.5 Verification Plan

The criteria for verification are defined within the Work Instruction within the WCN system. Upon completion of the Design Review Procedure the project manager is responsible to prepare the FAI reporting form.

7.2 Customer Focus

7.2.1 Determination of requirements related to the product

The CEO determines that all customer requirements are implementable and communicated clearly in accordance (QSP-720) Customer Focus. Customer requirements include:

- Quotation notes and requests by the customer,
- Delivery and post-delivery assessments,
- Requirements not stated by the customer but necessary for known and intended use,
- Statutory, regulatory and special requirements related to the product,
- Additional requirements determined by the CEO.

7.2.2 Review of Contract

The Customer Focus procedure is implemented within 48 hours upon receipt of order. This procedure is conducted before the order is accepted. The procedure ensures that:

- Product requirements are defined,
- Contract or order requirements differing from those previously quoted or expressed are resolved,
- Pacific Pattern Technologies has the ability to meet the defined requirements,
- Records are maintained showing the results of the review and any actions arising from the review,
- Contractual requirements are reviewed and special product requirements are determined,
- When product requirements are changed, the CEO communicates changes to relevant personnel and amends relevant documents by updating the WCN instruction and revision number and issuing a new Work Order Status (WOS) to the customer to signify acceptance of changes.
- Risks (e.g., new technology, short delivery time scale) have been evaluated.

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7.2.3 Acceptance of Contract

Customer requirements are determined and communicated to project managers in accordance with (QSP-720) Customer Focus.

The CEO ensures that customer requirements are understood clearly and met completely, by continually communicating to the customer via our Work Order Status (WOS).

The WOS communicates to the customer that the CEO has reviewed and recorded these items correctly:

- Purchase Order Information,
- Production data to be used,
- Customer Instructions,
- Regulatory Specifications,
- Key Characteristics.

7.2.3 Design Review and Customer Input

The WCN includes an excellent communication process to represent to the customer our manufacturing plan. The Design Review Acceptance form (DRA) is issued to the customer along with the exact as-machined model of the product for the customers' approval before production. All foreseen design issues and/or changes are documented and may require customer approval before continuing.

Additionally, upon customer request a model verification drawing and the FAI plan can be submitted for customer approval of our validation plan.

7.2.4 Customer Satisfaction

Each project is monitored using the WCN. Upon completion and delivery of each product to the customer there is a WCN closure meeting which also includes the 1-5 scoring of customers satisfaction and any complaints or issues that need to be resolved and addressed on future projects.

7.3 Design

7.3.1 Design planning

The design procedure (QSP-730) outlines the process for controlling the design process. The CEO plans engineering and design according to this procedure. The design plan includes these inputs:

- Internal design standards
- Customer design standards
- Customer Instructions
- Review of previous customer feedback
- Similar Projects

7.3.2 Design inputs

Inputs relating to product and customer requirements are determined and documented on form (QSF-711-05). The Project Manager is responsible to ensure that all inputs are reviewed for adequacy and completeness, and to resolve any ambiguous inputs according to the Design and Development procedure (QSP-730).

Inputs include:

- Purchase order instructions,
- Customer instructions,
- Applicable statutory and regulatory requirements,
- Where applicable, information derived from previous similar designs,
- Customer feedback from previous projects,
- Internal standards.

7.3.3 Design outputs

Design outputs are documented according to the Design Procedure (QSP-730). They are documented in a format that enables verification against the inputs, and are approved prior to release. Outputs:

- DRA, Design Review and Acceptance form for customers review of inputs,
- Concept and final design models for customer review and approval,
- Acceptance and verification or PO and identification criteria,
- If applicable operation instructions,

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- Verification of key characteristics in accordance with design or contract requirements (QSP-731) and action to be taken for these items,
- All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained is defined by the organization according to the Design Procedure (QSP-730).

7.3.4 Design review and acceptance

The design plan is reviewed by the customer before development can start in accordance with procedure (QSP-730). Communication to the customer is done utilizing a Design Review Acceptance form (DRA). Design reviews include:

- Evaluate the results of design outputs.
- Items requiring resolution, actions needed and the designee.
- Require customer inputs and final approval
- Finalize any delivery date issues

7.3.5 Design verification

Design verification is performed to ensure that the design outputs have satisfied the design input requirements and customer specifications. Records of the results of the verification and any necessary actions are maintained on the Design Review Acceptance (DRA) according to the Design and Development procedure (P-730).

7.3.6 Control of design changes

The design procedure (QSP-730) defines a process for identifying, recording, validating and approving design changes. The review of design changes includes an evaluation of the effect of the changes and delivery. Changes to a design that exceed the original purchase order and quotation specifications are subject to further quotation. Records and model revisions are maintained to show the results of the change and any necessary actions identified during the review.

7.4 Purchasing

7.4.1 Purchasing process

All purchases related to product development require a purchase order or ordering via website. The WCN number is the PO reference number for tracking product requirements and internal distribution to the correct project. A documented procedure Purchasing (QSP-740) is followed to ensure that

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purchased product conforms to the specified purchase requirements. All materials are purchased using form (QSP-711-004) Material Monitoring.

7.4.2 Purchasing information

Purchasing information describes the product to be purchased, including material and customer requirements in accordance with Purchasing Procedure (QSP-740).

7.4.3 Verification of purchased product

The Purchasing procedure (QSP-740) describes the process used to verify that purchased product meets specified purchase requirements.

All shippers are maintained by administration.

7.5 Product Development

7.5.1 Control of production

Pacific Pattern Technologies plans and carries out production under controlled conditions according to documented procedure (QSP-750). Controlled conditions include:

- Work Instructions
- Exact Manufacturing Models
- HAAS CNC equipment
- Measuring equipment
- Standardized tooling
- The accountability for all product during production, quantities, materials and progress
- Verification operations have been completed as planned, or as otherwise authorized,
- The monitoring and control of workmanship.

Planning considers, as applicable:

- The establishment of key manufacturing processes and development of control plans where key characteristics have been identified,
- The identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization,
- The design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics,

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- Special processes (see 7.5.2) and
- Special tooling and equipment.

7.5.1.1 Production Process Verification

Production processes are verified on each component before removal from CNC. All manufactured components require a full envelop inspection to ensure product is conforming and to monitor tool ware. Shop records are maintained for in-process verification in accordance with (QSP-750).

7.5.2 Control of Production Process Changes

Only the project manager is approved to change processes in production. The project manager controls and documents changes affecting processes, production equipment, tools and software programs via the WCN system according to the procedure (QSP-750).

The results of changes to production processes are verified per (QSP-750) to confirm that the desired effect has been achieved without adverse effects to product quality.

7.5.3 Control of Production Equipment, Tools and Software Programs

Production equipment, tools and programs are validated prior to use and 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, have been established for production equipment or tooling in storage.

7.5.4 Customer property

Pacific Pattern Technologies exercises care with customer property while it is under the organization's control or being used. A procedure (QSP-754) outlines the Identification, verification, protection and safeguarding of customer property provided for use.

7.6 Control of monitoring and measuring equipment

Pacific Pattern Technologies has determined the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

A register of monitoring and measuring equipment is maintained and the documented procedure (QSP-760) outlines the process used to ensure that monitoring and measurement to be carried out are carried out in a manner that is consistent with the monitoring and measurement requirements.

- Calibrated, verified or both at specified intervals against measurement standards traceable to international or national measurement standards.
- Adjusted or re-adjusted as necessary prior to use
- Identified to enable the calibration status to be determined
- Protected from damage and deterioration during handling, maintenance and storage
- Be recalled according to a defined method when requiring calibration

In addition, the CEO assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Pacific Pattern Technologies takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained

Pacific Pattern Technologies maintains a register of this monitoring and measuring equipment. The process used for their calibration is defined in procedures, work instructions and equipment manuals and includes details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This is undertaken prior to initial use and reconfirmed as necessary.

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

Section 8

Measurement, Analysis and Improvement

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8.1 General

Pacific Pattern Technologies plans and implements the monitoring, measurement, analysis and improvement processes as needed

- To demonstrate conformity of the product,
- To ensure conformity of the quality management system, and
- To continually improve the effectiveness of the quality management system.

These processes are identified in documented procedures and include determination of applicable methods and the extent of their use.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, Pacific Pattern Technologies monitors information relating to customer perception as to whether the organization has fulfilled customer requirements.

The information monitored and used for the evaluation of customer satisfaction includes, and is not limited to product conformity, on-time delivery performance, and customer complaints. Complaints or suggestions are photographed and/or documented in the project WCN system using (QSF-711-008) Customer Feed Back form. Improvements that address deficiencies are planned and implemented.

The method for obtaining and using this information is identified in the Customer Focus Processes (QSP-720).

8.2.2 Internal Audits

Pacific Pattern Technologies conducts internal audits on each procedure at random intervals to determine whether the quality management system and the procedures are implemented effectively.

An audit program has been designed and implemented and identifies an audit schedule based on the importance of the areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, are defined and documented in section 11.0 of each procedure.

The CEO is responsible for ensuring that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

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8.2.3 Monitoring and measurement of processes

Pacific Pattern Technologies applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product. In the event of process nonconformity, the organization follows the Control of Nonconforming Product and Process procedure (QSP-830) and:

- Takes appropriate action to correct the nonconforming process,
- Evaluates whether the process nonconformity has resulted in product nonconformity,
- Determines the scope of the process nonconformity,
- Determines if the process nonconformity is limited to a specific case or if it could have affected other processes or products, and
- Identifies and controls the nonconforming product in accordance with clause 8.3.

The process for identifying and carrying out the required monitoring and measuring of processes is documented in the Monitoring, Measuring and Analysis of Product Realization Processes (P-824).

8.2.4 Monitoring and measurement of product

Pacific Pattern Technologies monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process identified in Monitoring, Measuring and Analysis of Product Realization Processes (P-824). Evidence of conformity with the acceptance criteria is maintained.

Measurement requirements for product or service acceptance are documented. This documentation is part of the production documentation, and includes:

- Criteria for acceptance and/or rejection,
- A record of the measurement results, and
- Type of measurement instruments required and any specific instructions associated with their use.

When key characteristics have been identified, they are monitored and controlled. When the organization uses sampling inspection as a means of product acceptance, the plan is statistically valid and appropriate for use.

Product is not used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released unless it is identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

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Records indicate the person authorizing release of product, and provide evidence that the product meets requirements.

When required to demonstrate product qualification, records provide the evidence that defined requirements are met.

Pacific Pattern Technologies ensures that documents required by the contract or order to accompany the product are present at delivery and procedures implemented for the preparation and completion of Authority documentation.

8.3 Control of Nonconforming Product and Process

Pacific Pattern Technologies ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in the Control of Nonconforming Product procedure (P-830).

The term “nonconforming product” includes nonconforming product returned from a customer.

Responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions is defined in the procedure.

This process includes:

- Appropriate action to eliminate the nonconformity
- Disposition of the nonconforming material
- Taking action to control the material, precluding its original use
- Taking appropriate action when nonconforming product is detected after delivery
- Taking actions to contain the effect on other processes or products.

Corrected nonconforming product is re-verified and product dispositioned for scrap is conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

In addition to any contract or statutory and regulatory authority reporting requirements, Pacific Pattern Technologies system provides for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification includes a clear description of the nonconformity, which includes as necessary parts affected, customer and/or organization part numbers, quantity, and date(s) delivered.

Use-as-is disposition is only used with authorization by a representative of the design. The organization also does not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if

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- The product is produced to customer design, or
- The nonconformity results in a departure from the contract requirements.

8.4 Analysis of Data

Pacific Pattern Technologies determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

- Customer satisfaction
- Conformance to product and PO requirements
- Characteristics and trends of processes and products including opportunities for preventive action

8.4.1 Root Cause Analysis

In the event of defects or non-conforming product the disposition is determined by the CEO. The CEO additionally determines if root cause analysis should be performed. If it is determined a WCN is generated by the CEO specifically to be used for the analysis of non-conformity and the solution to resolve the error. Additionally (QSP-841) Root Cause Analysis procedure includes actions taken to ensure systems are updated to avoid future non-conformities.

8.5 Improvement

8.5.1 Continual improvement

Pacific Pattern Technologies continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. The CEO monitors the implementation of improvement activities and evaluates the effectiveness.

8.5.2 Corrective action

Pacific Pattern Technologies takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure (P-852) defines requirements for

- Reviewing nonconformities (including customer complaints),
- Determining the causes of nonconformities,
- Evaluating the need for action to ensure that nonconformities do not recur,
- Determining and implementing action needed,
- Records of the results of action taken (see 4.2.4), and
- Reviewing the effectiveness of the corrective action taken.
- Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause,
- Specific actions where timely and/or effective corrective actions are not achieved,
- Identification of additional nonconforming product,
- Root cause is determined as needed (P-841)

8.5.3 Preventive action

Pacific Pattern Technologies determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure (P-853) defines requirements for:

- Determining potential nonconformities and their causes
- Evaluating the need for action to prevent occurrence of nonconformities
- Determining and implementing action needed
- Records of results of action taken
- Reviewing the effectiveness of the preventive action taken

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Related Documents

WCN	P711
Customer Related Processes	P-720
Monitoring, Measuring and Analysis of Customer Satisfaction	P-821
Internal Audits	P-822
Monitoring and Measuring of Product and Realization Processes	P-824
Control of Nonconforming Product	P-830
Statistical Techniques	P-840
Root Cause Analysis	P-841
Corrective Action	P-852
Preventive Action	P-853

QUALITY SYSTEM MANUAL REVISIONS

REV.	SECTION	SUB-SEC.	PARA.	CHANGE REQUEST #	DATE	AUTHORIZED BY
NC					06-23-17	G Turner`