



**PRO Engineering**

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2480 Kruse Dr  
San Jose, CA 95131

# Quality Manual

**Quality Policies Manual**

Revision A, 08.31.2006

**Quality Procedures Manual**

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**PRO Engineering  
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<b>PRO Engineering QUALITY MANUAL</b>		
Section 1	PURPOSE AND SCOPE	Page 1 of 1

**1.1 Purpose**

The purpose of the Quality Manual is to document the Quality Management System used by PRO Engineering to assure the quality of its products and services for its location at 2480 Kruse Dr., San Jose, CA 91131 meets customer and applicable requirements.

**1.2 Scope**

**1.2.1 General**

The scope of the Quality Management System described in the Quality Manual includes only the activities and operations of PRO Engineering.

This scope is: Precision machining as milling, turning, prototype, production and assembly of mechanical parts to customer requirements.

PRO Engineering provides products that will meet the statutory and regulatory specifications and drawing requirements as stated and required by the customers.

PRO Engineering is a contract company and provides resources and training as required to implement, maintain and improve the quality system, products and services on an ongoing basis.

The PRO Engineering Quality Management System is relevant to the nature of our Company and to customer and regulatory requirements.

**1.2.2 Application**

The Quality Management System described in the Quality Manual applies to all work undertaken by PRO Engineering. Requirements of Design and Development are excluded from the scope of our quality system. PRO Engineering does not design products. Instead, customers specify all product characteristics. Our activities are limited to developing methods and means of products and services.

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PRO Engineering was founded in 1998 by Bart Teciorowski and is located in San Jose, CA. It employs a team of highly skilled professionals who operate a state-of-the-art manufacturing facility.

With its continual commitment to the improvements of the quality system and the assurance of conformity to customer requirements as well as through the commitment to on-time deliveries and personalized customer service, PRO Engineering continues to achieve the highest ratings from a valuable and loyal customer base.

PRO Engineering specializes in precision manufacturing, CNC, milling and turning to customer specifications. Our top quality precision parts are used by the electronic, medical, packaging and aerospace industries. PRO Engineering customers include large semiconductors companies, companies working for airlines as well as small business companies in Bay Area.

We are committed to continuously improving the quality of products and services provided, and operations for the benefit of all our customers.

To achieve our policy we will:

1. Identify and deliver best value solutions that satisfy the requirements of our customers
2. Acquire, develop and retain a diverse workforce of multi-skilled performers
3. Provide a positive work environment that offers rewarding opportunities to employees

We, the Company's managerial team are proud of our record of providing such an indispensable service and in our belief of our company and service.

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Section 3

TERMS AND DEFINITIONS

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PRO Engineering will identify and define terms that describe our Quality Management System and are used in this Quality Manual. Defined terms apply to internal and/or external processes. These terms, and the context they are used in, are crucial for proper understanding of the Quality Manual as well as Quality Procedures.

**Terms and Definitions**

- **Audit** – systematic, independent and documented examination process for obtaining and evaluating evidence of compliance with planned arrangements and their implementation, in order to determine to what extent the criteria are fulfilled.
- **Audit Criteria** – set of policies, procedures or requirements used as reference.
- **Audit Evidence** – records, statements of fact or other information, which are relevant to the audit criteria and verifiable.
- **Capability** – ability of an organization, system or process to realize a product that will fulfill the requirements for that product.
- **Competence** – demonstrated ability to apply knowledge and skills.
- **Conformity** – fulfillment of a requirement.
- **Continual Improvement** – recurring activity to increase the ability to fulfill requirements.
- **Contract** – requirements agreed to between a supplier and a customer, transmitted by any means.
- **Corrective Action** - action to eliminate the cause of a defected nonconformity or other undesirable situation.
- **Customer** – organization or a person that receives a product.
- **Customer Complaint** – any reported allegation, written or verbal, from a customer of deficiencies related to the identity, quality, durability, reliability safety or performance of a product or service.
- **Customer Satisfaction** – customer’s perception of the degree to which the customer’s requirements have been fulfilled.
- **Document** – information and its supporting medium.
- **Effectiveness** – extent to which planned activities are realized and planned results achieved.
- **Final Inspection Report** – document listing certain, critical dimensions, notes and/or features for which actual results are to be recorded.

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- **First Article Inspection (FAI)** – the inspection process used in verifying a part being built or reviewed for the first time in accordance with the specified requirements. This could also include changes in revisions, specifications, part numbers, subcontractors, or machines used to manufacture the product.
- **Infrastructure** – organization system of facilities, equipment and services needed for the operation of an organization.
- **Inspection** – conformity evaluation by observation and judgment accompanies as appropriate by measurement, testing or gauging.
- **Management System** – system to establish policy and objectives, and to achieve those objectives.
- **Management Representative (MR)** – person designated by the President to represent the company in matters related to ISO 9001-2008 requirements, with the responsibility and authority to implement changes for compliance.
- **Manager** – the person, who exercises authority, takes responsibilities, makes decisions and fulfils similar managerial functions on behalf of the business.
- **Nonconformity** – non-fulfillment of a requirement.
- **Objective Evidence** – data supporting the existence of verity of something.
- **Preventive Action** – action to eliminate the cause of a potential nonconformity or other undesirable potential situation.
- **Procedure** – a document that describes specifically how an activity is to be performed. It may include methods to be used, equipment to be used and sequence of operations.
- **Process** – set of interrelated or interacting activities, which transforms inputs to outputs.
- **Product** – the physical good or service that is the output (result) of a process.
- **Purchase Order (P/O)** – a contract defining and identifying the specified requirements of a given product.
- **Quality Assurance** – part of quality management focus on providing confidence that quality requirements will be fulfilled.
- **Quality Management System (QMS)** – management system to direct and control an organization with regard to quality.
- **Quality Manual** – document specifying the quality management system of an organization.

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- **Quality Objective** – something sought or aimed for, related to quality.
- **Quality Policy** – overall intentions and direction of an organization related to quality as formally expressed by top management.
- **Record** – document stating results achieved or providing evidence of activities performed.
- **Requirement** – all stated and implied criteria, which must be met to satisfy market demands.
- **Specification** – a detailed and precise statement of the features of a product (part or assembly) including prescribed materials, dimensions, and workmanship for something built, assembled or manufactured.
- **Supplier** – organization or person that provides a product or material.
- **Test** – determination of one or more characteristics according to a procedure.
- **Top Management** – person or group of people who directs and controls an organization at the highest level.
- **Traceability** – ability to trace the history, application or location of that which is under consideration.
- **Validation** – confirmation, through the provision of objective evidence, that the requirements for a specific intended use of application have been fulfilled.
- **Verification** - confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.
- **Work Environment** – set of conditions under which work is performed.

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Section 4

QUALITY MANAGEMENT SYSTEM

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**4.0 Scope and Purpose**

This manual has been prepared to satisfy the requirements of our customers for Quality Management System and for all activities carried out by the Company.

The responsibility and authority for overall administration of the Quality Management System activities is shared by top management, including the President and Quality Manager/Management Representative.

The effective implementation of the Quality Management System is verified by regular inspections, reviews and audits that compare management practice against the requirements of the written procedures. Corrective actions are taken where necessary and are subsequently reviewed for effectiveness.

**4.1 General Requirements**

PRO Engineering through the offices of the President is committed to maintaining an effective Quality Management System.

To implement the Quality Management System our company has:

- identified the processes needed for the Quality Management System and their application throughout the organization;
- determined the sequence and interaction of these processes;
- determined the criteria and methods needed to ensure that both the operation and control of these processes are effective;
- ensured the availability of resources and information necessary to support the operation and monitoring of these processes internal and external;
- established a method of monitoring, measuring and analyzing of these processes; and,
- implemented actions necessary to achieve planned results and continual improvement of these processes.

These processes are controlled to ensure control over any outsourced processes that affect product conformance with requirements. Control of such applicable processes is identified within the Quality Management System.

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## **4.2 Documentation Requirements**

### **4.2.1 General**

The PRO Engineering Quality Management System documentation includes the following:

- a Quality Manual,
- documented statement of a Quality Policy and Quality Objectives,
- documented procedures,
- documents required by our company to ensure the effective planning, operation and control of its processes,
- records

### **4.2.2 Quality Manual**

This Quality Manual, as written, defines the scope of the PRO Engineering Quality Management System including details of, and justification for permissible exclusion.

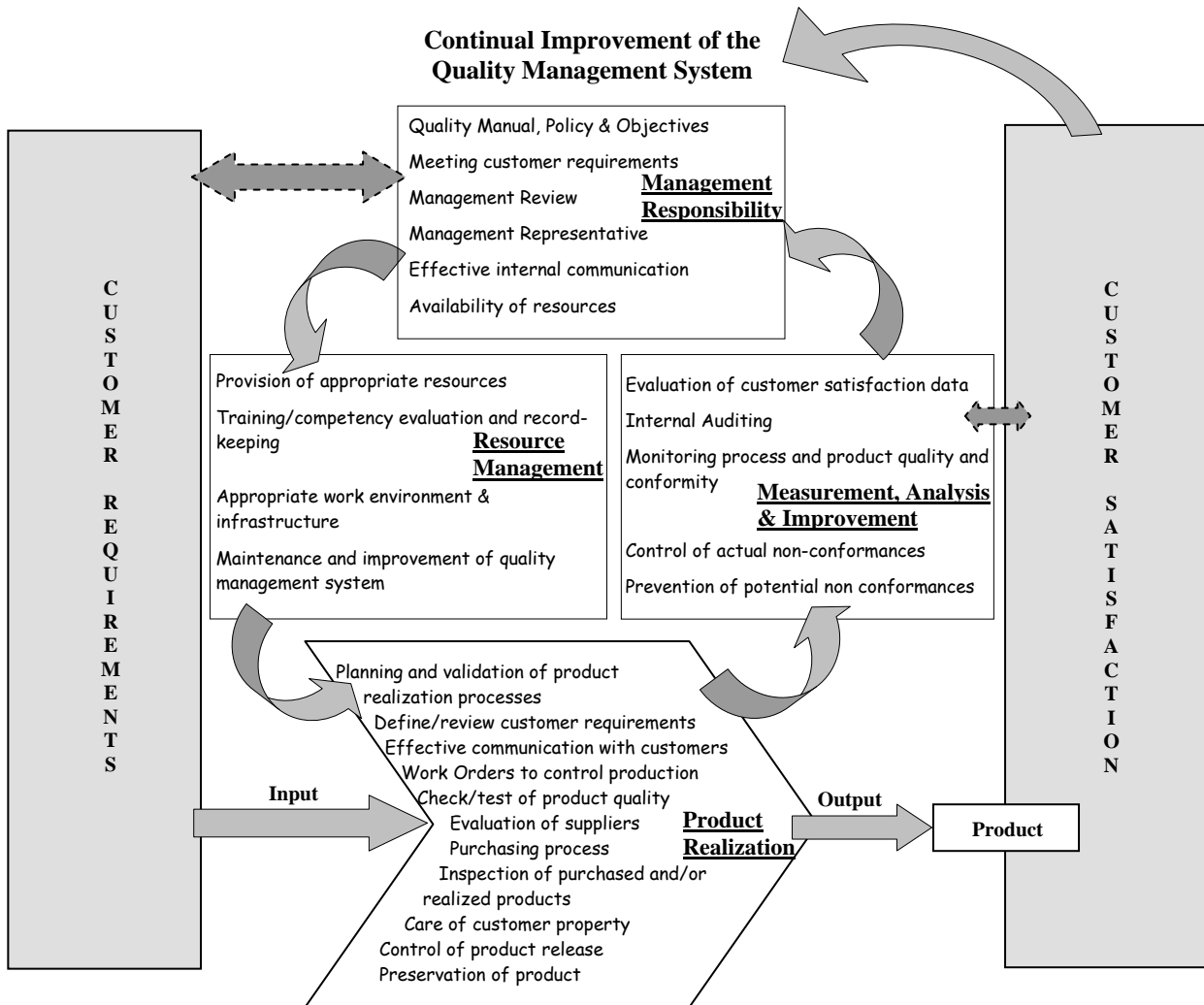
The documented procedures established for this Quality Management System will be identified and referenced to the Quality Manual.

Interaction between the processes of the PRO Engineering Quality Management System are described by the Model of a Process-Based PRO Engineering Quality Management System included below.

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**PRO Engineering Model of a Process-Based Quality Management System**



**Key**

➡ Value-adding activities

➡ Information flow

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### 4.2.3 Control of Documents

Documents and records required by the Quality Management System are controlled. A documented procedure has been established to define the controls needed to:

- approve documents for adequacy prior to issue,
- review and update as necessary and re-approve documents,
- ensure that changes and the current revision status of documents are identified,
- ensure that relevant versions of applicable documents are available at points of use,
- ensure that documents remain legible and readily identifiable.

Quality Operational Procedure No. QOP-420, Documents Control and Records, implements this policy.

### 4.2.4 Control of Quality Records

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the Quality Management System.

Records shall be legible, readily identifiable and retrievable.

The activities of identification, collection, indexing, filing, storage, maintenance and disposition of Quality Records are accomplished by documented procedure QOP-420, Documents Control and Quality Records.

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**5.0 Scope and Purpose**

Quality Policy (Ref. 5.3 of this Section) reflects top management commitment. Management Commitment is established via Planning, Customer Focus, Management Responsibility, Authority and Communications. Management Review is performed at regular intervals.

**5.1 Management Commitment**

Top management has provided evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- establishing the Quality Policy
- ensuring that quality objectives are established
- conducting management reviews and ensuring the availability of resources
- communicating the importance of meeting customer requirements as well as regulatory requirements to the company’s employees

The President leads company personnel in a committed effort to provide the resources and management for the review of all sources in order to ensure the effectiveness and continual improvement of the quality management system.

Ref. QOP-560, Management Review.

**5.2 Customer Focus**

Top management has ensured that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction.

All customer orders and/or contracts are reviewed to assure the customer’s requirements are adequately defined and understood, and that the company has the capability to meet contractual requirements.

Ref. QOP-722, Order/Contract Review

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Section 5

MANAGEMENT RESPONSIBILITY (Continued)

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**5.3 Quality Policy**

Top management has ensured the quality policy is appropriate to the purpose of the Company and includes a commitment to comply with requirements and continual improvement of the effectiveness of the business and quality management system.

Top management has ensured the policy is communicated to all employees and is understood within the company.

Quality Policy will be reviewed periodically and revised as necessary to be consistent with our business policies.

PRO Engineering Quality Policy Statement is:

**PRO Engineering is committed to Quality Management System that leads us to providing quality products, continually satisfy our customers and improve our business. We demonstrate this commitment through continuous improvement of our quality system, processes, products and services.**

Our Quality Objectives for Production parts are:

- ◆ To deliver manufactured products always on time
- ◆ To find all nonconforming products internally
- ◆ To avoid any rejections of our products by customers

**Our Quality Objectives for Prototype parts are:**

**Responsiveness to Customer requests and changes to drawings and its designs**

**Find any non-conformance internally and avoid any rejections by customers**

Approved and Signed by:

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Quality Management System will allow our company to meet the requirements of our customers and standards.

The **President** and **Quality Manager**(Management Representative) are responsible for any matters pertaining to quality, and have the authority to recommend and implement quality changes to the system.

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## **5.4 Planning and Quality Objectives**

### **5.4.1 Quality Objectives**

Top management has ensured that quality objectives, including those needed to meet requirements for product,, are established at relevant functions and levels within company. Management has considered current and future needs of the company, relevant findings from management reviews, current product and process performance, and levels of satisfaction of interested parties.

The quality objectives are measurable and consistent with the quality policy.

### **5.4.2 Quality Management System Planning**

Top management has ensured that the planning of the Quality Management System is carried out in order to meet the general requirements of quality systems standards and that the integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented.

## **5.5 Responsibility, Authority and Communication**

### **5.5.1 Responsibility and Authority**

Top management has ensured that the responsibilities and authorities are defined and communicated within the company.

The company employees have been given responsibilities and authority that enables them to contribute to the achievement of the quality objectives and to establish their involvement, motivation and commitment.

Ref. Appendix A, Organizational Charts.

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## 5.5.2 Management Representative

Top management has appointed a **Quality Manager** as Management Representative. Irrespective of other responsibilities this person has responsibility and authority to ensure that processes needed for quality management system are established, implemented and maintained.

Management Representative(QA Manager) will report to the Company President on the performance of the quality management system, any need for its improvement, and for ensuring the awareness of customer requirements throughout the company.

Management Representative shall act as a liaison between company and external parties on matters relating to the quality management system.

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## 5.5.3 Internal Communication

Top management has ensured appropriate communication processes are established within the company and that communication takes place regarding the effectiveness of the quality management system.

President actively encourages feedback and communication from employees as a means of involving them into continual improvement of quality management system.

## 5.6 Management Review

Top management reviews the PRO Engineering Quality Management System at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the Quality Management System, including the Quality Policy and Quality Objectives.

Records of Management Review are maintained.

Ref. QOP-560, Management Review.

### 5.6.1 Management Review Input

Management Review includes review of all appropriate Quality Management System documentation including the results of audits, customer feedback, process performance and product conformity, status of corrective and preventive actions, follow-up from previous management reviews, changes that could affect the quality management system, and recommendations for improvement.

### 5.6.2 Management Review Output

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Management Reviews conducted by top management shall provide an official outline including any decisions and actions related to the improvement of the quality management system and its processes, improvement of product related to customer requirements, and resource needs.

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## **6.0 Scope and Purpose**

PRO Engineering will provide human resources and maintain an infrastructure and work environment that will enhance its resources through awareness and training. Assignment of personnel shall be based upon competence, awareness and training.

### **6.1 Provision of Resources**

PRO Engineering management has determined and provided the quality resources needed to implement and maintain the Quality Management System, continually improve its effectiveness, and to enhance customer satisfaction by meeting customer requirements.

### **6.2 Human Resources**

#### **6.2.1 General**

PRO Engineering Management will ensure on the basis of appropriate education, training, skills and experience that personnel performing work affecting product quality is competent. Applicant applied for work will be interviewed, tested and put on probation period of work. All new employees, at any level, must undergo a Quality Induction Session. The purpose of this session is to generate an awareness of the company's total commitment to quality management system, including its Quality Policy and Procedures, and to indoctrinate new employees in the benefits of working within the quality system.

If it is realized that current employees need their skills improvement, these needs will be identified and training will be provided. Only qualified personnel will perform specific tasks.

#### **6.2.2 Competence, Awareness and Training**

The management team shall determine the necessary competence for personnel performing work affecting product quality and provide training or take other actions to satisfy these needs.

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Training and actions taken will be evaluated to determine the effectiveness of the actions taken and to ensure that staff understand the relevance and importance of their activities and how they contribute to the process.

Personnel qualifications documents and training records are maintained.

### **6.3 Infrastructure**

PRO Engineering determines, provides and maintains the infrastructure needed to achieve the conformity to product requirements. Infrastructure includes as applicable: building, workspace and associate utilities, process equipment (hardware & software), and supporting services (such as transport or communication).

### **6.4 Work Environment**

The work environment needed to achieve conformity to product requirements has been determined and is managed.

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## **7.0 Scope and Purpose**

PRO Engineering will provide plan for the processing of products and processes that will satisfy or exceed expectations of our customers. All purchased products and/or materials will meet applicable safety and regulatory requirements of the customer.

### **7.1 Planning of Product Realization**

In planning of product realization PRO Engineering will determine the requirements for the products and quality objectives. PRO Engineering will establish processes, documents, and provide resources specific to the product.

If product required outside processes PRO Engineering shall provide oversight for the manufacturer of the product and/or surveillance of contracted manufacturing.

Required verifications, validations, monitoring, inspection and test activities specific to the product and the criteria for PRO Engineering will determine product acceptance.

Records needed to give evidence that the realization processes resulting in product meeting requirements shall be provided.

PRO Engineering personnel is provided with instructions when complex or important activities warrant it. Company equipment, processes, product characteristics and production environment are controlled and/or maintained.

Ref. QOP-710, Planning of Product Realization.

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## **7.2 Customer-related Processes**

### **7.2.1 Determination of Requirements Related to the Product**

PRO Engineering will be proactive in determining of customer needs. Each customer P.O./Contract will be carefully reviewed and all statutory and regulatory requirements will be adhered to with all products.

PRO Engineering will determine:

- if requirements specified by the customer can be met, possibly including the requirements for delivery and post-delivery activities,
- if requirements not stated by the customer but necessary for specified or intended use are known,
- if there are any additional requirements determined necessary by our Company based on experience, knowledge and history of the product.

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### **7.2.2 Review of Requirements Related to the Product**

PRO Engineering will review the requirements related to the product. The review shall be conducted prior to the company's commitment to provide a product to the customer and shall ensure that: a) product requirements are defined, b) contract/ order requirements differing from those previously expressed are resolved and accepted, and c) the Company will make sure that has the ability to meet the defined requirements.

Where the customer provides no documented statement of requirements, our Company before acceptance of the tender shall receive customer requirements confirmed in writing.

Where product requirements are changed, the Company will ensure that changes received from the customer are to be clearly identified, relevant documents are amended and that relevant personnel are made aware of the any changes or modifications.

Records of the results of the review and actions arising from the review shall be maintained per Section 4.2.4, Control of Quality Records.

Ref. QOP-722, Order/Contract Review.

### **7.2.3 Customer Communication**

PRO Engineering will determine and implement effective arrangements for communicating with customers throughout documented system in relation to product information, inquiries,

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contracts or order handling (including amendments), and customer feedback (including customer complaints).

### **7.3 Design and Development**

Design and Development is not within the scope of PRO Engineering business practices. PRO Engineering, does no in-house design. All work is done to the specifications of customer provided specifications.

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### **7.4 Purchasing**

#### **7.4.1 Purchasing Process**

PRO Engineering purchases only from suppliers and vendors that satisfy the Company quality requirements.

Purchasing documents completely describe ordered products, including quality requirements. Purchasing documents are reviewed and approved before they are released.

All Purchasing is generated thru E2 MRP software.

The Company separates between suppliers and vendors. Suppliers deliver standard hardware or products, while vendors perform certain operations according to drawings provided by our Company as well as special services that cannot be done at PRO Engineering.

Purchasing & Finance Department carry out the evaluation of suppliers and vendors.

The quality performance of suppliers and vendors is monitored. Suppliers with inadequate performance are asked to implement corrective actions as described in QOP-8.5.2, Corrective Action. They are disapproved if there is no improvement.

A Preferred Supplier/Vendor List is maintained in E2 MRP Software and used by QA, Production and Finance Departments. Orders are only placed with suppliers from this list. Excluded from the list are any materials, tools and office supplies with no influence on product quality.

Ref. QOP-740, Purchasing.

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## 7.4.2 Purchasing Information

Purchasing documents clearly and completely describe ordered products.

They are generated thru E2 MRP software.

They include identification of the products, reference applicable standards and state quality requirements when required.

Rules for preparation, review and approval of purchasing documents are provided in QOP-740, Purchasing.

## 7.4.3 Verification of Purchased Product

PRO Engineering has established and implemented activities necessary for ensuring that purchased product meets specified purchase requirements.

The Company's customers are given the right to verify by themselves that the purchased products conform to specified requirements. The verification does not absolve the organization from responsibility to deliver a quality product.

Ref. QOP-740, Purchasing.

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## 7.5 Production and Service Provision

### 7.5.1 Control of Service Provision

PRO Engineering has established and maintains service provisions under controlled conditions. These conditions include the availability of information that describes the characteristics of the product, applicable work instructions as necessary, the use of suitable equipment, monitoring and measuring devices as arranged, the implementation of monitoring and measurement as well as implementation of release, delivery and post-delivery (if applicable) activities.

A Shop Traveler that specifies the company service steps will be issued and it will serve as control of all necessary phases of product realization. The Shop Traveler lists operations necessary to create and verify a product. Shop Traveler and the accompanying documents (if applicable) will be filled out by operating personnel.

### 7.5.2 Validation of Processes for Production and Service Provision

PRO Engineering will validate processes for service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies may become apparent only after the product is in use or the service has

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been delivered. Validation shall demonstrate the ability of the processes to achieve planned results. PRO Engineering will define criteria for review and approval of the processes, for approval of equipment and qualification of personnel, for use of specific methods and procedures, and will establish requirements for records and revalidation (as applicable).

Personnel performing processes will be provided with work instructions and workmanship criteria if necessary.

Records for qualified processes, equipment and personnel will be maintained.

### 7.5.3 Identification and Traceability

Products are identified throughout whole process by technical drawing which contains part number, part name, and job order number.

All relevant documentation is to be cross-referenced as required to provide positive identification of materials acquisition and at all stages of process production and delivery.

Traceability is provided to the documentation that PO/contract specify.

All inspections are recorded and signed off by personnel performing them.

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### 7.5.3 Identification and Traceability (continued)

Formal and detailed traceability system is used only if required by a relevant standard, inspecting authority or as a contractual condition, i.e. serialization, lot number, etc.

Production Department maintains the job files with associated documentation for all jobs. Files contain also a quality records and are available when required by customer.

### 7.5.4 Customer Property

Customer's property can be handled in a different manner from other material or products purchased for production or incorporation manufactured goods into the final product because of customer requirements. When specified in a contract, special handling instructions from customers will take precedent over our company standard procedures. Customer property is received, identified by marking or labeling, inspected and stored and maintained to prevent damage in a designated area, separated from PRO Engineering owned material or hardware.

Loss, damage or unsuitability of customer property is recorded and reported to the customer with written report, and records are maintained.

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### 7.5.5 Preservation of Product

Methods and means of handling that prevent product damage or deterioration are provided. Receipt and dispatch to and from storage areas are controlled. The condition of stored products is specified and controlled. Products are protected prior to and during delivery.

Handling areas and their operation are the responsibility of the company President. He is also responsible for ensuring the containers and equipment used for transportation and storage are adequate, clean, and adequate for protection of product during storage and delivery.

The packaging and shipping personnel have the responsibility for preservation of products during packaging. Specifications are communicated to the shipping personnel on the Work Traveler and/or in the form of work instructions. Packaging and preservation is designed for the intended means of delivery.

Methods for preservation and segregation of product are applied throughout packaging and delivery processes.

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### 7.6 Control of Monitoring and Measuring Devices

All measuring and test equipment is calibrated with traceability to the National Institute of Standards and Technology. Calibration certificates are maintained and the calibration status of measuring equipment is identified. The equipment is well maintained and its placement and use are controlled.

QA Department maintains a list of measuring and test equipment specifying the identity, location and calibration status for each piece. An outside accredited calibration facility is used at the discretion of the QA Manager. Calibration of some measuring instruments can be performed internally according to Work Instruction PROE-WI-004, In-House Calibration.

QA Department maintains and is responsible for equipment used for suitable inspection tests, and for checking it prior to initial use to prove that equipment is capable of verifying the acceptability of product. QA Department maintains certifications of outside calibration lab and all relevant documentation. Items are checked every 1-year or 6 month as applicable.

Activities related to this section are regulated by QOP-760, Control of Measuring Equipment.

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Section 8

MEASUREMENT, ANALYSIS AND IMPROVEMENT

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## **8.0 Scope and Purpose**

PRO Engineering will plan and implement the measurement and monitoring activities used to ensure conformity of the Quality Management System to specified requirements and to provide its continual improvement.

### **8.1 General**

Activities to which QMS monitoring, measurement, internal audit and data analysis will be applied are: customer satisfaction, quality management system performance, processes conformance and conformance of product.

When appropriate, statistical techniques as the collection, analysis, interpretation and presentation of obtained data are used to provide information for continual improvement.

### **8.2 Monitoring and Measurement**

#### **8.2.1 Customer Satisfaction**

Customer feedback data is collected and reviewed periodically in order to maintained customer satisfaction data, and to provide input for continual improvement.

Customers' Satisfaction is also examined periodically.

#### **8.2.2 Internal Audit**

Planned and documented Internal Quality Audits are carried out according to the Audit Plan. Audits are scheduled on the basis of status and importance of the activity.

The Quality Manager/Management Representative establishes an internal audit plan and schedule in accordance with QOP-822, Internal Audit. Every activity and area is audited at least once a year, but more frequent audits can be scheduled if required.

If possible, personnel that are independent of the audited activities are assigned to conduct an audit. The Quality Manager normally leads the audits, but QA activities are audited by the Production Department personnel. Audits are prepared by a review of quality records, and activities are described in QOP-822, Internal Audit.

If nonconforming conditions are identified, the manager responsible for the affected area or activity proposes and implements a corrective action. Implementation and effectiveness of this action is verified by a follow-up audit.

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Conduct and documentation of audits and follow-ups are described in QOP- 822, Internal Audit.

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### **8.2.3 Monitoring and Measuring of Processes**

PRO Engineering shall apply suitable methods for monitoring and where applicable, measurement of the Quality Management System processes. These methods shall demonstrate the ability of the processes to achieve planned results.

When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

One of methods to monitor processes is conducting Internal Audits (Ref. Sect. 8.2.2 and QOP-822).

### **8.2.4 Monitoring and Measuring of Product.**

PRO Engineering will monitor and check the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements.

Evidence of conformity with the acceptance criteria will be maintained. Records shall indicate the person(s) authorizing release of product.

Product release and service delivery shall not proceed until all the planned arrangements (Ref. Section 7.1 – Planning of Product Realization) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

## **8.3 Control of Nonconforming Product**

PRO Engineering will ensure 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 a documented procedure QOP-830, Control of Nonconforming Product.

Nonconforming products will be dealt with by one or more of the following ways: by taking action to eliminate the detected nonconformity, by authorizing its use, release or acceptance under concession by a relevant authority, and where applicable, by the customer.

Records of the nature of nonconformities and any subsequent actions taken shall be maintained. When nonconforming product is corrected, it shall be subject to re-inspection to demonstrate conformity to the requirements.

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The responsibility for disposition of nonconforming product is defined (Ref. QOP-830, Control of Nonconforming Product) and when required, the customer will be acknowledged.

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## **8.4 Analysis of Data**

PRO Engineering shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the Quality Management System and to evaluate where continual improvement of the QMS can be made. This shall include data generated as a result of monitoring and measuring and from other relevant sources as customers' reports, internal receiving inspection logs, production statistics, etc.

The analysis of data shall provide information relating to customer satisfaction, conformity to products requirements, suppliers performance, and characteristics and trends of processes including opportunities for preventive action.

[Ref. QOP-840, Analysis of Data](#)

## **8.5 Improvement**

### **8.5.1 Continual Improvement**

The Quality Management System is managed in a manner to offer continual improvement having regard to statements in its Quality policy, objectives, audit results, data analysis, corrective and preventive action and management review. The Quality Management System is reviewed at least two times yearly to assure its continuing effectiveness.

Ref. QOP-560, Management Review

### **8.5.2 Corrective Action**

Corrective action is crucial to the PRO Engineering Quality Management System. Complaints regarding nonconformities that may lead to potential quality problems shall be investigated, and effective corrective action implemented.

Anyone in the organization may request corrective action but only the Quality Manager or the Company President can initiate corrective action.

Corrective Action is initiated as the result of:

- Identification of product nonconformity
- Process quality problems
- Noncompliance observed during audits
- Customer complaints
- Nonconforming deliveries from suppliers or vendors (subcontractors)

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- Bad housekeeping or any practice affecting quality

Ref. QOP-852, Corrective and Preventive Action

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### 8.5.3 Preventive Action

PRO Engineering will determine actions to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

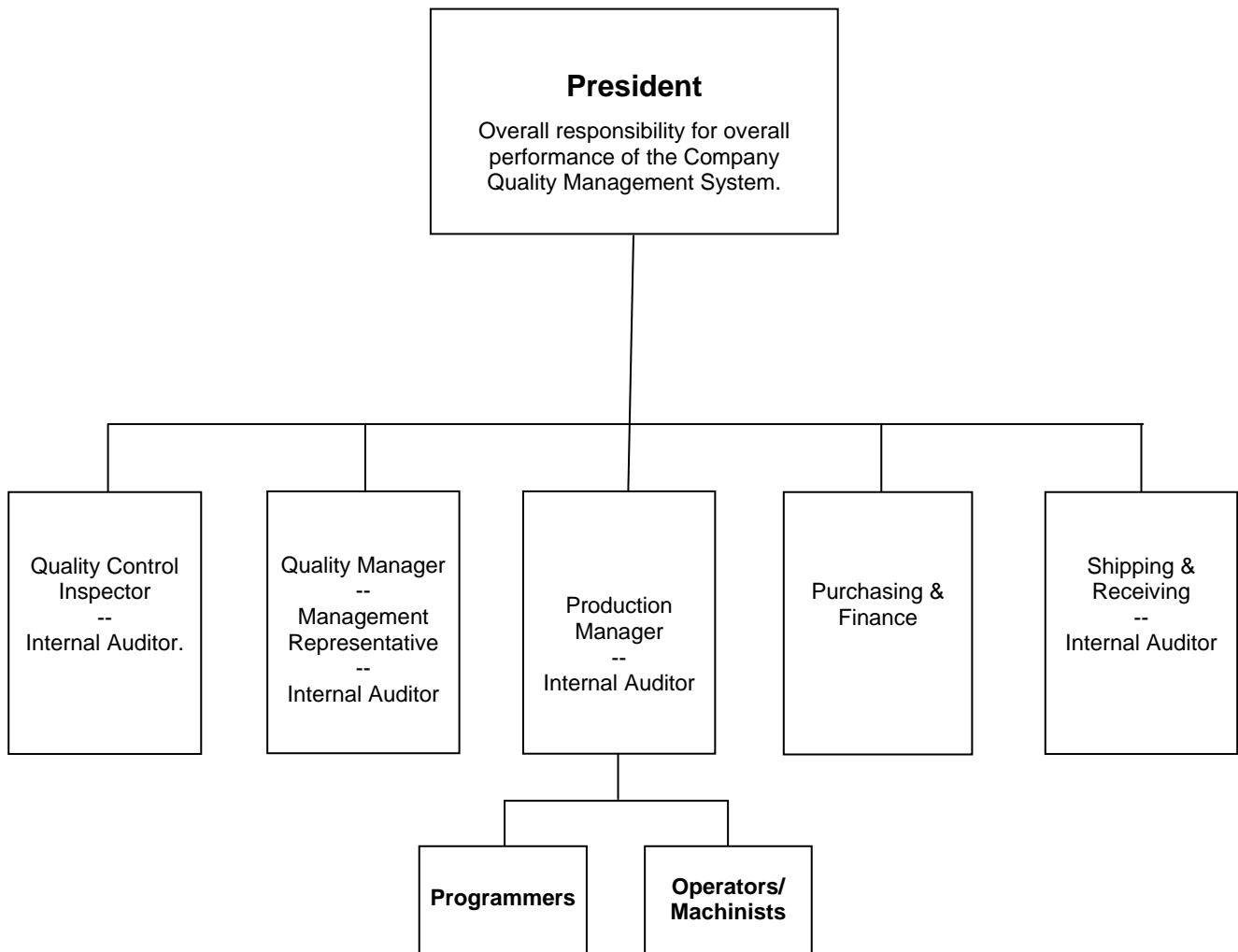
The documented procedure has been established to define requirements for determining potential nonconformities and their causes, the evaluation for action to prevent occurrence of nonconformities, determining and implementing action needed, records of results of action taken and reviewing preventive action taken.

Ref. QOP-852, Corrective and Preventive Action.

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**1. ORGANIZATIONAL CHART**



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**PRO Engineering  
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Quality Manuals marked/stamped “Controlled Copy” are distributed to Company departments’ managers, authorities and customers with contract provisions. These Manuals are registered with consecutive numbers in Controlled Circulation List of the Quality Manual (below) by Quality Manager/Management Representative to expedite the update service when revisions take place. With this process copies are only given to specific persons.

Departments’ managers follow the outlined polices relevant to their processes.

CONTROLLED CIRCULATION LIST OF THE QUALITY MANUAL

<u>Copy No.</u>	<u>Copy Custodian</u>	Department/Organization
1.	Quality Manager/Management Representative	Quality Assurance Department
2.	President	PRO Engineering President

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APPENDIX C

AMENDMENT RECORD

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**Amendments**

This Quality Manual contains only the pages issued by this facility. The Quality Manager will process all authorized changes (Ref. QOP 420, Documents Control and Records) and insert amendment pages into the officially distributed copies (recorded on Controlled Circulation List of this Quality Manual, Appendix B, page 1 of 1). The Quality Manager also will make sure that all down level and/or obsolete pages are withdrawn from use and disposed of to prevent unintentional usage.

Each change is recorded in Table of Amendments (below).

This copy of the Quality Manual becomes a Controlled Copy document when unique number and its custodian is assigned. The Master Copy of this Quality Manual is maintained by the Quality Manager also in electronic version. The Master Copy shall be used as the final authority regarding the latest revision level and amendment status for the PRO Engineering.

TABLE OF AMENDMENTS

Date	Section/ Page	Description of Changes	Old Rev.	New Rev.	Approval
08.31.06	All	Initial Issue of Quality Manual	-	A	Bart Teciorowski
05.13.09	All	Minor re-wording and misspelling corrections		A	Bart Teciorowski

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