



---

# Quality Manual



### 1.0 Scope

*Performance Technologies designs and manufactures innovative and comprehensive hardware, software and solutions for the world's evolving communications infrastructure.*

### 1.1 General

This Quality Manual address the requirements of the ISO 9001 Standard. All reference to the ISO 9001 Standard forward shall be considered as the current revision of the ISO 9001 Standard. The Quality Manual defines the Quality Management System as it applies to Performance Technologies locations in Rochester, New York, San Diego, California and San Luis Obispo, California. Performance Technologies locations in Ottawa, Canada is listed as the exclusion to this manual within section 2.0 Normative Reference.

### 1.2 Corporate Overview

Performance Technologies was formed in 1981 under the laws of the state of Delaware and maintains its corporate offices at 205 Indigo Creek Dr. Rochester, New York 14626. In January of 1996, Performance Technologies announced a public offering and began trading its common shares on the NASDAQ National Market under the trading symbol "PTIX".

Performance Technologies and its subsidiaries develop platforms, components and software solutions for the world's evolving communications infrastructure. Our broad customer base includes companies in the communications, commercial and military markets. Serving the industry for over 20 years, our complete line of packet-based products enables equipment manufacturers and service providers to offer highly available and fully-managed systems with time-to-market, performance and cost advantages.

### 1.3 Introduction

This manual contains three introductory sections, numbered 1.0 to 3.0 and five process definition sections numbered 4.0 to 8.0. All eight sections correspond to the ISO 9001 Standard. Supporting documentation is identified and referenced within their corresponding section of this manual.

Unless otherwise defined, the definition of terms used within this manual are described in the ISO 9001 Standard. Other definitions are contained within the Terms and Definitions section of this manual.



**1.3 Regulation**

**1.3.1 Control**

Any changes and/or distribution of this Quality Manual are controlled and approved by the Director of Quality.

**1.3.2 Distribution**

A controlled hard copy of this manual resides within Documentation Control in Rochester, New York. No other controlled hard copies are distributed. Controlled electronic versions of this Quality Manual reside within the corporate server and corporate website. Updates are distributed to all authorized controlled copy recipients. Uncontrolled copies of this Quality Manual may be distributed to approved recipients. Uncontrolled copies are not included under the controlled Quality Manual circulation and are therefore not updated. Distribution of Quality Manuals is subject to approval of the Director of Quality. Reproduction in whole or in part of this Quality Manual without the consent of Performance Technologies is prohibited.

**1.3.3** This Quality Manual has two options for distribution as stated below:

This manual is provided under controlled distribution. A Part Number and Revision Level has been assigned and controlled updates are provided as they occur to the following individual.

Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

This manual is not on a controlled distribution and is not updated as changes occur.

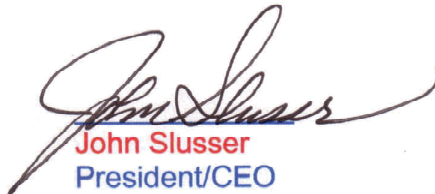
**1.3.4 Revisions**

Requests for changes to this Quality Manual can be submitted by any employee of Performance Technologies. Each Request for Change must be submitted to the Director of Quality of Performance Technologies. Revisions to the Quality Manual are at the discretion of the Director of Quality.

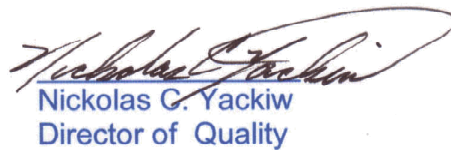


**1.4 Approvals**

We hereby certify that the contents of this Quality Manual accurately and adequately describe the Quality System in use within Performance Technologies and approve its contents.



John Slusser  
President/CEO



Nickolas G. Yackiw  
Director of Quality

Reproduction in whole or in part of this Quality Manual without the consent of Performance Technologies Incorporated is prohibited.



Table of Contents

<u>Description</u>	<u>Page</u>
<b>1.0 Scope &amp; Corporate Overview</b>	2
Regulation	3
Approvals	4
Table of Contents	5
Revision Control	6
Exclusions	7
<b>2.0 Normative Reference</b>	8
<b>3.0 Terms and Definitions</b>	9
<b>4.0 Quality Management System</b>	
4.1 General Requirements	10
QMS Flow Chart	11
4.2 Documentation Requirements	12-13
<b>5.0 Management Responsibility</b>	
5.1 Management Commitment	14
5.4 Planning	15
5.5 Responsibility, Authority and Communication	16
5.5.1 Organization Chart	17
5.5.2 Responsibility Matrix	18
5.6 Management Review	19
<b>6.0 Resource Management</b>	
6.1 Provision of Resources & Human Resources	20
6.3 Infrastructure & Work Environment	21
<b>7.0 Product Realization</b>	
7.1 Planning of Product Realization	22
7.2 Customer Related Processes	23
7.3 Design and Development	24-28
7.4 Purchasing Process	29
7.5 Production and Service Provision	30
7.5.2 - 7.5.5 Production and Service Provision cont.	31
7.6 Control of Monitoring and Measuring Devices	32
<b>8.0 Measurement, Analysis and Improvement</b>	
8.0 Measurement Analysis and Improvement	33
8.2.2 Internal Quality Audits	34
8.2.3 - 8.2.4 Monitoring and Measurement of Processes	35
8.3 Control of Nonconforming Product	36
8.4 Analysis of Data	37
8.5 Improvement	38
8.5.2 Corrective Action	39
8.5.3 Preventive Action	39



## Quality Manual Revision Control 081A0001XX

Note: The last two digits of the Quality Manual Part Number represents the revision.

Revision	Reason	Documents Affected	DCN	Date
10-19	Reference previous revision "Quality Manual Revision Control" document. (Rev 19 or below)			
20	Updated 5.1 Management Commitment	081A000120	080A002058	05/31/2007
21	Updated Quality System Flow Chart	081A000121	080A002082	06/27/2007
21	Removed SLO from Exclusions	081A000121	080A002082	06/27/2007
21	Updated Organizational Chart	081A000121	080A002082	06/27/2007
22	Updated Quality Policy	081A000122	080A002173	01/03/2008
23	Updated Organizational Chart	081A000123	080A002312	06/25/2008
24	Updated 7.2 Customer Related Process	081A000124	080A002334	08/28/2008
24	Updated 7.4 Purchasing Process	081A000124	080A002334	08/28/2008
24	Updated 7.5 Production & Service	081A000124	080A002334	08/28/2008
25	1.1 Scope & Corporate Overview - ISO9001:"2000" Removed	081A000125	080A002855	10/21/2010
25	1.6 Revision Control - ISO9001:"2000" Removed	081A000125	080A002855	10/21/2010
25	1.7 Exclusions - ISO9001:"2000" Removed	081A000125	080A002855	10/21/2010
25	2.0 Normative Reference -ISO9001:"2000" Removed	081A000125	080A002855	10/21/2010
25	3.0 Terms and Definitions -ISO9001:"2000" Removed	081A000125	080A002855	10/21/2010
25	4.1 Quality System General Requirements - ISO9001:"2000" Removed	081A000125	080A002855	10/21/2010
25	4.2 Documentation Requirements - ISO9001:"2000" Removed	081A000125	080A002855	10/21/2010
25	5.1 Management Commitment - ISO9001:"2000" Removed	081A000125	080A002855	10/21/2010
25	5.5.5 Responsibility Matrix - ISO9001:"2000" Removed	081A000125	080A002855	10/21/2010



## **Exclusions**

Performance Technologies Division in Ottawa, Canada is not presently certified to the ISO9001 standard and is excluded from the Rochester ISO9001 certification. Products designed at the Ottawa facility are manufactured in Rochester and are manufactured under ISO9001 certification.



## 2.0 Normative Reference

The following document contains provisions which, through reference in this manual, constitute provisions of the International Standard.

ISO 9001, Quality management systems-Requirements

The latest revision of this document applies.



<b>ANSI/ASQC Q9001.</b> American National Standard corresponding to the International Standard ISO 9001.	<b>Assembly.</b> Result of putting together at minimum two piece parts.
<b>Conforming.</b> Meets established drawings or specifications.	<b>CAR.</b> Corrective Action Report.
<b>DMR.</b> Discrepant Material Report.	<b>DCN.</b> Document Change Notice.
<b>ESD.</b> Electrostatic Discharge.	<b>FDDI.</b> Fiber Distributed Data Interface.
<b>IPC.</b> The Institute for Interconnecting and Packaging Electronic Circuits.	<b>Manufacturing.</b> Making of goods, encompassing production, installation, and servicing.
<b>Material.</b> Piece parts or subassemblies that feed the higher level product.	<b>MRB.</b> Material Review Board.
<b>Nonconforming.</b> Product/material that does not conform to established drawings or specifications.	<b>Pareto Analysis.</b> In its simplest form, a listing in order of importance.
<b>Product.</b> The result of production. Product may include raw material, partially completed work in process assemblies, and finished goods.	<b>RFC.</b> Request for Change.
<b>RMA.</b> Return Material Authorization.	<b>Subcontractor.</b> Outside contractor who manufactures assemblies to Performance Technologies, Incorporated specifications.
<b>SBus.</b> I/O bus designed by Sun Micro-Systems.	<b>SPC.</b> Statistical Process Control.
<b>Transferred Employee.</b> Employee moved from one production work center into another.	<b>Vendor.</b> A distributor or Manufacturer from whom, piece parts are purchased.
<b>VME.</b> Versa Module European (Specifications of Backplane Signals)	<b>QMS.</b> Quality Management System



#### 4.1 Quality System General Requirements

Performance Technologies has established, documented, implemented and maintains an effective Quality Management System conforming to the requirements of ISO 9001. The Quality System is designed to continually improve its effectiveness and efficiency of the organization's performance and satisfy our customers' requirements.

Performance Technologies has:

- identified the processes needed for establishment of the Quality Management System and their application throughout the organization. (reference 7.1 Planning of Product Realization);
- determined the sequence and interaction of these processes. (reference 7.1 Planning of Product Realization);
- determined criteria and methods needed to ensure that both the operation and control of these processes are effective. (reference 7.5.1 Control of Production and Service Provision);
- ensured the availability of resources and information necessary to support the operation and monitoring of these processes. (reference 6.1 Provision of Resources);
- established measures or metrics to monitor, measure and analyze these processes. (reference 8.2 Monitoring and Measurement);
- where necessary, implemented actions necessary to achieve planned results and continual improvement of these processes. (reference 8.2 Monitoring and Measurement and 8.5 Improvement)

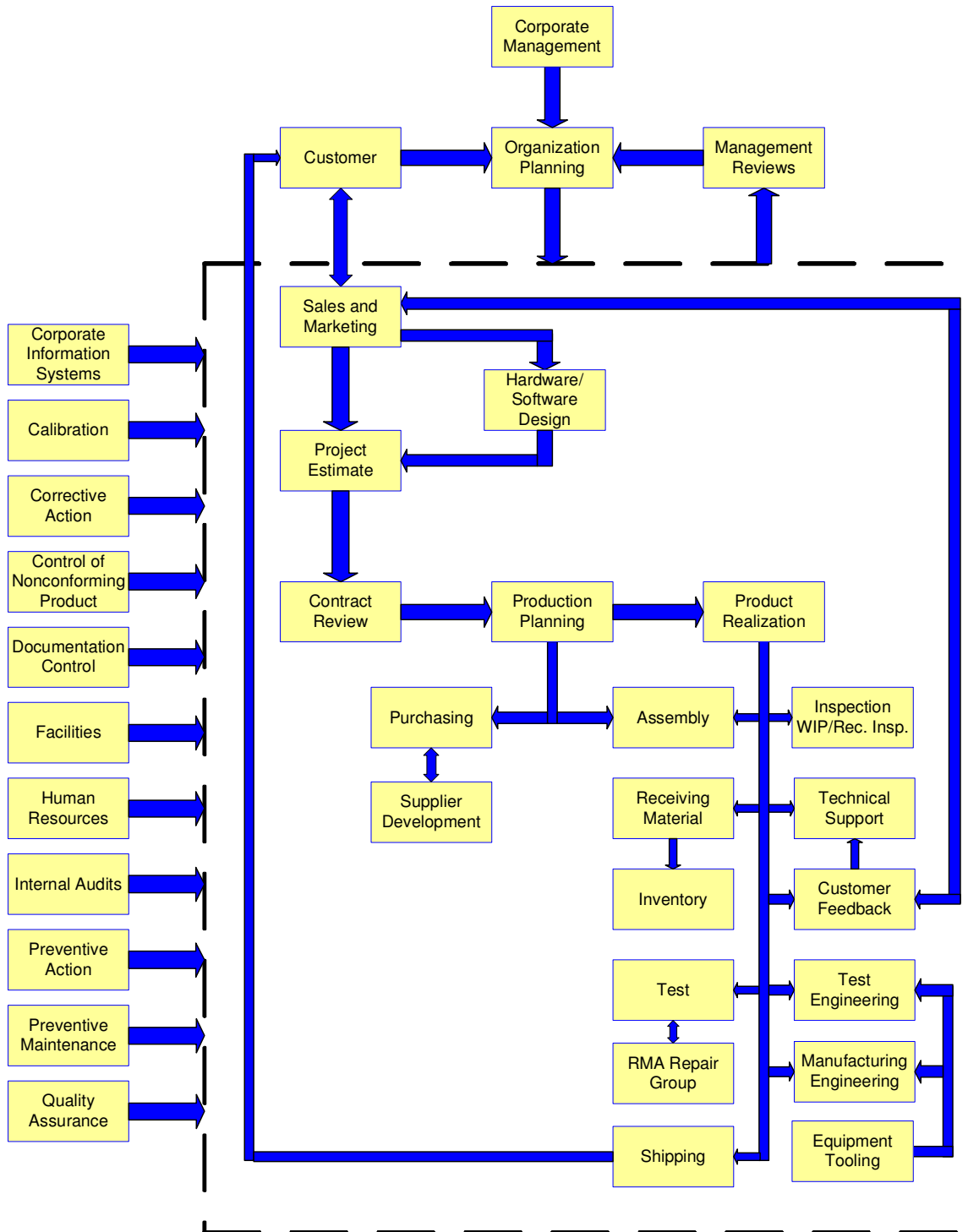
Where Performance Technologies chooses to outsource any process that may affect product conformity to requirements shall be controlled through inspection of the product or supplier.

#### Supporting Documentation

- Quality System Procedure
- Management Responsibility Procedure
- Planning of Product Realization Procedure



Figure 1





## 4.2 Documentation Requirements

### 4.2.1 General

A documentation system has been established by Performance Technologies which consists of the Quality Manual, supporting documentation, and relevant records that are required to support effective planning, operation and control of the organizations processes. Performance Technologies quality manual has been reviewed by management, where applicable, and is approved by the President and Management Representative as indicated in the approval section within this manual.

A quality policy has been created to define the purpose of the organization and lead the organization towards continual improvement of its performance. The quality policy is continually reviewed at management review meetings for its continuing suitability. (reference 5.3 Quality Policy)

Performance Technologies top management establishes corporate quality objectives in line with the strategy of the company. Corporate quality objectives are measurable and consistent with the corporate quality policy. Additional Quality Objectives are established at relevant levels within the company. (reference 5.4 Planning)

The Quality Management System is comprised of four levels of documentation that are organized in a pyramidal fashion, as defined by the diagram below. The four levels of documentation include the Quality Manual, procedures, work instructions, and quality system forms and databases (Records).



### 4.2.2 Quality Manual

This Quality Manual defines the eight requirements of the ISO 9001 standard as it pertains to Performance Technologies. The Quality manual contains the scope of the quality system and justification for any exclusions, a description of quality system processes and their interrelation's, and references to supporting documentation.

#### Supporting Documentation

- Document and Data Control Procedure
- Control of Quality Records Procedure



## 4.2 Documentation Requirements (continued)

### 4.2.3 Control of Documents

Performance Technologies requires that all documents comprising the Quality Management System are controlled. Procedures and processes have been established to define the controls:

- documents must be approved prior to use;
- documents must be reviewed and updated as necessary, and re-approval is required;
- changes and current revision status of documents are identified;
- relevant versions of applicable documents are available at points of use;
- documents must be legible, readily identifiable and retrievable;
- documents of external origin are identifiable and their distribution controlled;
- to prevent the unintended use of obsolete documents, suitable identification is applied if they are retained for any purpose.

**Note:** Any typographical errors and minor editorial changes are not considered as changes for the purpose of this quality manual.

### 4.2.4 Control of Records

Performance Technologies has developed a procedure to define the controls needed for records. Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records are legible, readily identifiable and retrievable. The identification, storage, protection, retrieval, retention time and disposition of records are documented within the Control of Quality Records Procedure listed in supporting documentation. Individual departmental records not included within the Control of Quality Records Procedure are defined within their respective departmental procedure.

### Supporting Documentation

- Document and Data Control Procedure
- Control of Quality Records Procedure



### 5.1 Management Commitment

Performance Technologies management is committed to the development of the quality management system by adopting and certifying the quality management system to the requirements of ISO 9001. Management is committed to utilizing and improving the effectiveness of the quality management system in order to meet customer and regulatory requirements.

Performance Technologies management is committed to the development and implementation of the Quality Management System and to continually improve its effectiveness by:

- communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- establishing a Quality Policy;
- establishing quality objectives;
- conducting management reviews; and
- ensuring the necessary resources.

### 5.2 Customer Focus

Performance Technologies Management ensures customer requirements are understood and evaluated and that the company's products are designed and manufactured to meet or exceed their requirements with the aim of enhancing customer satisfaction. Customer requirements are documented through a process defined within the Sales Support procedure. Unique customer requirements are defined as "custom" product and included within the Sales Support procedure.

### 5.3 Quality Policy Statement

***It is the policy of Performance Technologies to meet or exceed our customer requirements and expectations in a cost effective manner. This is accomplished through our corporate quality program, continuous improvement and the dedicated effort of all employees.***

#### Supporting Documentation

- Management Responsibility Procedure
- Sales Support Procedure



## **5.4 Planning**

### **Quality Objectives**

Performance Technologies management has ensured that quality objectives, including those needed to meet the requirements for products are established within specific departments in the organization. Quality objectives are measurable and are consistent with the quality policy. Records of quality system objectives are documented electronically and are updated by management or the appointed management representative.

### **Quality Management System Planning**

Performance Technologies top management ensures that:

- the planning of the quality management system is carried out in order to meet the requirements given in 4.1 as well as the quality objectives: and
- the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Quality management system planning is within the framework of Management Review meetings. Data presented at the management review meetings is used to provide input for quality planning and continual improvement. Quality planning may include, but is not limited to:

- quality objectives;
- the process of the quality management system;
- the resources needed;
- continual improvement of the quality management system.

### **Supporting Documentation**

- Management Responsibility Procedure



## 5.5 Responsibility, Authority and Communication

### 5.5.1 Responsibility and Authority

Management ensures that responsibilities and authorities are defined and communicated within the organization. Department Responsibilities and authorities are documented in their respective processes and are indicated in the Responsibility Matrix and organizational chart within this Quality Manual. (reference 5.5.4 Organizational chart and 5.5.5 Responsibility Matrix)

### 5.5.2 Management representative

Top management has appointed a management representative who, irrespective of other responsibilities, has the responsibility and authority that includes:

- ensuring that processes needed for the quality management system are established, implemented and maintained;
- reporting to top management on the performance of the quality management system, and any need for improvement; and
- ensuring the promotion of awareness of customer requirements throughout the organization.
- the potentially act as liaison with external parties on matters relating to the quality management system.

The President has assigned the responsibility and authority of the management representative to the Director of Quality. The Director of Quality has the authority for establishment and approval of all processes and their related documentation within the Quality Management System. The Director of Quality is responsible to report the performance of the quality system including proposal of potential improvements through management review meetings.

### 5.5.3 Internal communication

Top management ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. Performance Technologies maintains a corporate wide electronic network supplying multiple means of electronic communication including:

- Documentation control
- Email
- Corporate Website
- Databases

In addition to electronic media, Performance Technologies utilizes additional means of communication listed but not limited to:

- corporate newsletter
- internal meetings
- staff meetings
- bulletin boards
- voice communication system

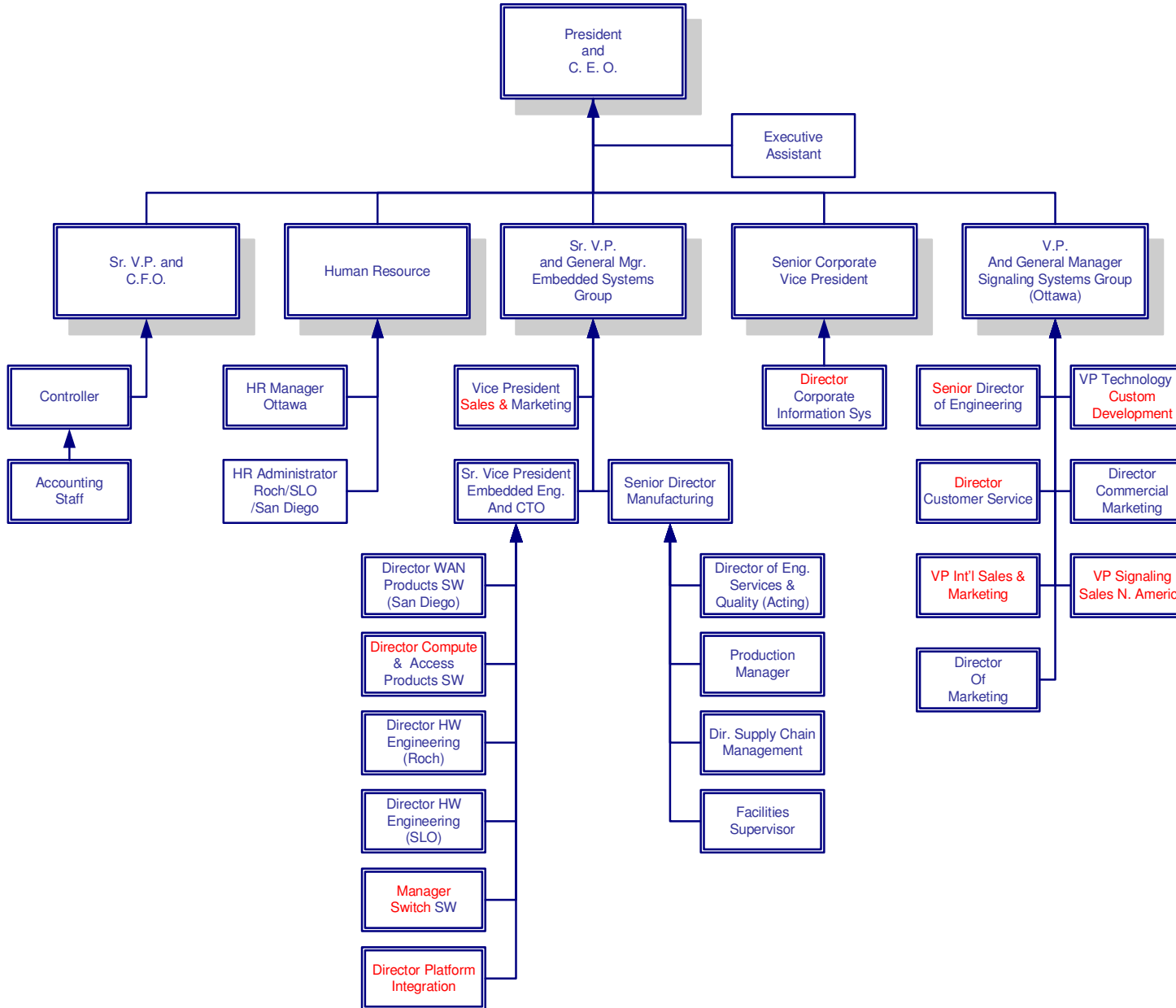
### Supporting Documentation

- Management Responsibility Procedure
- Documentation Control Procedure

- Control of Quality Records Procedure



5.5.4 Organizational Structure





**5.5.5 Responsibility Matrix**

Individual responsibilities are documented in their respective procedure or work instruction. In the following matrix one or more departments is assigned the responsibility (Noted by a "X")

ISO9001 Requirements	Section	Mgt	Desg	CIS	Doc. Ctrl	Mat	Mfg. Eng.	Test Eng	Sch. & Plan	Prod.	Test Group	Q.A	Q.C	H.R.	Service	Facilities	Mkt	Sales
Doc. Req.	4.2			X	X													
Mgt. Commitment	5.1	X																
Customer Focus	5.2	X																
Quality Policy	5.3	X																
Planning	5.4	X																
Responsibility, Authority and Communication	5.5	X																
Management Review	5.6	X																
Provision Resources	6.1	X																
Human Resources	6.2													X				
Infrastructure	6.3	X																
Work Environment	6.4	X																
Planning of Product Realization	7.1	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Customer Related Processes	7.2																	X
Design and Development	7.3		X															
Purchasing Process	7.4					X												
Production and Service Provision	7.5					X	X	X		X	X			X				
Control of Monitoring and Measuring Devices	7.6											X	X					
Measurement Analysis and Improvement	8.1	X									X	X		X				
Monitoring and Measurement of Processes	8.2											X			X			
Control of Nonconforming Product	8.3												X					
Analysis of Data	8.4	X										X			X			
Improvement	8.5	X										X						



## 5.6 Management Reviews

Top management reviews the quality management system, at planned intervals, ensuring its continuing stability, adequacy and effectiveness. The review includes assessing opportunities for improvement and the need for changes to the quality management system, including quality policy and quality objectives. Records from top management reviews are maintained.

Management review inputs and outputs are defined within the Management Responsibility Procedure. Management review meetings are scheduled by the management representative and held at least once per calendar year. Meeting minutes, action items, corrective actions and preventive actions are recorded and distributed accordingly as a result of the meeting.

### Supporting Documentation

- Management Responsibility Procedure



## 6.1 Provision of Resources

Performance Technologies determines and provides the resources needed:

- to implement and maintain the quality management system and continually improve its effectiveness, and
- to enhance customer satisfaction by meeting customer requirements.

Management identifies resource requirements through the corporate budget process. Corporate budgets and personnel requirements are based upon corporate sales targets. Adequate resources, including management and personnel performing engineering and verification activities, is provided through the use of Human Resources.

## 6.2 Human Resources

Performance Technologies personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience.

### Competence, Awareness and Training

Performance Technologies

- determines the necessary competence for personnel performing work affecting product quality;
- provides training or take other actions to satisfy those needs;
- evaluates the effectiveness of the actions taken;
- ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives;
- maintains appropriate records of education, training, skills, and experience.

Performance Technologies has established and maintains a system that utilizes job descriptions, resumes, and training records to determine the necessary competence of the employee and competence level requirements of a particular position. The system determines the employee competence needs and provides the required training to satisfy those needs when a deficiency occurs. Employees are made aware of the importance of their activities, and how they contribute to achieving quality objectives by the orientation process for new employees and by employee performance reviews.

### Supporting Documentation

- Human Resource Procedure



### 6.3 Infrastructure

Performance Technologies has determined, provides, and maintains an infrastructure needed to achieve conformity to product requirements. This infrastructure includes:

- Buildings, workspace, and associated utilities
- Process equipment, both hardware and software
- Supporting services (i.e. communication)

Management has provided facilities, work spaces, tools, equipment, and associated utilities necessary to achieve conformity to product requirements and ensure employee health and safety in the work place.

### 6.4 Work Environment

Performance Technologies has determined and maintains its facilities based upon the identification and management of the human and physical factors of the work environment needed to achieve product conformity. These factors include but are not limited to:

- lighting, temperature, and cleanliness
- Electrostatically controlled environment in appropriate areas.

### Supporting Documentation

- Equipment Maintenance Procedure
- Facilities Procedure
- ESD - Electro Static Discharge Procedure



## 7.1 Planning of Product Realization

Performance Technologies has planned and developed the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the quality management system. (reference 5.1)

In planning product realization, Performance Technologies determines the following as appropriate:

- Quality objectives and requirements for the product;
- The need to establish processes, documents, and provide resources specific to the product;
- Required verification, validation, monitoring, inspection, and test activities specific to the product and the criteria for product acceptance;
- Records needed to provide evidence that the realization processes and resulting product meet requirements

Planning of product realization is initiated within the design phase of a product. Objectives and requirements for the product are established and documented through the use of the Product Planning Document. Product requirements are released to manufacturing for process development. Production and test processes are developed taking into consideration the appropriate verification, validation, monitoring, inspection, and test activities. Appropriate records are created and maintained.

### Supporting Documentation

- Design and Development Planning Procedure
- Control of Quality Records Procedure
- Test Engineering Procedure
- Manufacturing Engineering Procedure



## 7.2 Customer Related Processes

### Determination of Requirements Related to the Product

Performance Technologies customer requirements, including statutory and regulatory, as well as organizational requirements, are an important input to the product realization process. They are defined during the early phases of product development. These include:

- Requirements specified by the customer, including the requirements for delivery and post delivery activities;
- Requirements not stated by the customer but necessary for specified or intended use, where known;
- Statutory and regulatory requirements related to the product;
- Any additional requirements determined by Performance Technologies

### Review of Requirements Related to the Product

Performance Technologies has established and maintains documented processes for the review of the requirements related to the product. Prior to the commitment to deliver product to the customer, the requirements are reviewed to ensure that:

- the product requirements are defined and where no written statement of requirement is available for an order, Performance Technologies ensures that the order requirements are agreed upon before their acceptance.
- Any differences between the contract or accepted order requirements, and those in tender are resolved;
- Performance Technologies has the capability to meet contract or accepted order requirements.

Customer requirements are reviewed to insure they are adequately defined and documented during the contract review process prior to order acceptance. Standard product contracts are inputted into the corporate system as customer purchase orders following review and acceptance. Custom product contracts are handled separately from standard product. Product Management has the responsibility of custom products. Product Management reviews customer requirements and assess the capability to produce the product while consulting with the appropriate affected organizations. Custom product contracts are inputted into the corporate system following Product Management review and acceptance. (reference [Sales Support Procedure](#))

### Supporting Documentation

- [Sales Support Procedure](#)



### 7.3.1 Design and Development Planning

Performance Technologies plans and controls the design and development of the product. During the design and development planning, the organization determines:

- the design and development stages,
- the review, verification and validation that are appropriate to each design and development stage, and
- the responsibilities and authorities for design and development,

The organization manages the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibilities. Planning output is updated, as appropriate, as the design and development progresses.

Design and Development Planning is a process followed throughout a project's execution to provide for the following, but not limited to;

- Definition of distinct stages that a project follows through its lifecycle.
- Definition of the processes to be followed throughout the project lifecycle, including review, verification and validation processes.
- Control and insight into the project's status for PTI Management.
- Clear definition of responsibilities and authorities with regard to each aspect of the design and development process.
- Clear definition of the interfaces (with respect to deliverables) between the various departments involved in the project.

#### Supporting Documentation

- Hardware Design Procedure
- Software Design Procedure
- Design and Development Planning Procedure



### 7.3.2 Design and Development Inputs

Inputs relating to product requirements have been determined and records maintained (reference 4.2.4). These inputs include:

- functional and performance requirements,
- applicable statutory and regulatory requirements,
- where applicable, information derived from previous similar designs, and
- other requirements essential for design and development.

These inputs are reviewed for adequacy. Requirements are complete, unambiguous and not in conflict with each other.

Performance Technologies has defined the inputs for the Design and Development cycle. These inputs include but are not limited to;

- Functional and performance requirements determined from customer quotations and or proposals;
- Identification of any statutory and regulatory requirements as defined within the Project Plan.
- Review of previous designs or customer requirements and suggestions for product changes for applicable information.

Design and Development Inputs include all of the information available that affects the design and development process. These inputs come from both external and internal sources.

#### Supporting Documentation

- Hardware Design Procedure
- Software Design Procedure
- Design and Development Input Procedure
- Design and Development Planning Procedure



### 7.3.3 Design and Development Outputs

Performance Technologies outputs of design and development are provided in a form that enables verification against the design and development input and is approved prior to release. Design and development outputs:

- meet the input requirements for design and development,
- provide appropriate information for purchasing, production and for service provision,
- contain or reference product acceptance criteria, and
- specify the characteristics of the product that are essential for its safe and proper use.

Performance Technologies has defined the outputs of the Design and Development cycle. These outputs include but are not limited to;

- Documentation packages including Bills of Materials, assembly drawings, schematics and user manuals. Packages become available to manufacturing at time of release.
- Product acceptance criteria which is defined by the documentation package as well as diagnostic code for testing and product verification.
- Product usage information as defined by product user manuals which includes setup, configuration and usage information.

#### Supporting Documentation

- Hardware Design Procedure
- Software Design Procedure
- Design and Development Input Procedure
- Design and Development Output Procedure



**7.3.4 Design and Development Review** Design and Development Planning is a process followed throughout a project's execution to provide for the following;

- Definition of the processes to be followed throughout the project lifecycle.
- Control and insight into the project's status for PTI Management.
- Clear definition of responsibilities and authorities with regard to each aspect of the design and development process.
- Clear definition of the interfaces (with respect to deliverables) between the various departments involved in the project.

Performance Technologies performs design reviews at suitable stages. Systematic reviews of design and development is performed in accordance with planned arrangements (reference 7.3.1). These reviews are performed to:

- to evaluate the ability of the results of design and development to meet requirements, and
- to identify any problems and propose necessary actions.

Participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions are maintained (reference 4.2.4).

Performance Technologies Design Engineering reviews each design project based on the design plan. Formal design reviews are documented through the use of the Design Review Checklist.

#### **Supporting Documentation**

- Hardware Design Procedure
- Software Design Procedure
- Design and Development Planning Procedure



### 7.3.5 Design and Development Verification

Performance Technologies performs design verification in accordance with planned arrangements (reference 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions are maintained (reference 4.2.4).

Performance Technologies verifies product designs by performing functional diagnostic tests that assess the product's output compliance to the design specifications. Product verification is performed prior to delivery of the product to ensure that the product has met the requirements stated in the Project Plan.

### 7.3.6 Design and Development Validation

Performance Technologies design and development validation is performed in accordance with planned arrangements (reference 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use where known. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained (reference 4.2.4).

Product validation is performed prior to wide-spread deployment of the product. Validation is typically performed as part of a Beta cycle at a real customer site. The purpose of validation is to demonstrate that the product design meets the requirements stated in the Project Plan and its intended application.

### 7.3.7 Control of Design and Development Changes

Performance Technologies design and development changes are identified with records maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions are maintained (reference 4.2.4).

Hardware design changes occurring during the design and development cycle are tracked and controlled by the design review process and documentation revision control. Software design changes occurring during the design and development cycle are tracked, controlled, and documented in the Incident Report Database. Design changes on product following release, either initiated by Performance Technologies or requested by the customer, are reviewed and implemented by the Document Change Notice (DCN) process.

#### Supporting Documentation

- Hardware Design Procedure
- Software Design Procedure
- Document and Data Control Procedure



#### 7.4 Purchasing

Performance Technologies has established a process to ensure that purchased material conforms to internal specifications and customer specified requirements, if applicable. Purchasing, Design Engineering, and Quality Assurance are responsible for selecting vendors and subcontractors based on their ability to meet the specified requirements.

Performance Technologies selects, evaluates and re-evaluates all suppliers based on their ability to meet requirements. The selection of suppliers is based upon any or all of the following: technical competence, product availability, product cost, product quality, reputation, reference checks, quality system audits, financial stability, and past and present performance history. Records of supplier evaluations including supplier performance are maintained.

The requirements for purchased material are clearly specified on the Purchase Order. These requirements may include references to specifications, drawings, revisions, method of acceptance, applicable personnel and equipment requirements. Purchasing documents are reviewed and verified prior to release. If source inspection is required by Performance Technologies or by our customer, verification and acceptance arrangements are identified within the purchase order or contract.

#### Supporting Documentation

- Purchasing Procedure
- Quality Control Inspection Procedure
- Sales Support Procedure



## 7.5 Production and Service Provision

### 7.5.1 Control of Production and Service Provision

Performance Technologies plans and carries out production and service provision under controlled conditions. Controlled conditions include, as applicable

- the availability of information that describes the characteristics of the product;
- the availability of work instructions, as applicable;
- the use of suitable equipment;
- the availability and use of monitoring and measuring devices;
- the implementation of monitoring and measurement, and
- the implementation of release, delivery and post-delivery activities.

Instructions have been documented and implemented for all areas of production and service allowing production and service to be carried out under controlled conditions. Documents offering instruction to production and service are electronically maintained and controlled by revision and release. Examples of these documents include, but are not limited to, the following:

- Sales orders
- Work orders
- Production Travelers
- Departmental procedures and work instructions
- Production process instructions
- Test instructions
- Inspection instructions
- Service (RMA) instructions

Equipment suitable to produce and verify the quality of the product is maintained, calibrated and documented. Performance Technologies has implemented suitable release mechanisms to ensure product and service conforms to specified requirements.

#### Supporting Documentation

- Process Control Procedure
- Manufacturing Engineering Procedure
- Quality Control Inspection Procedure
- Test Engineering Procedure
- Service Procedure
- **Factory Repair Procedure**



### 7.5.2 Validation of processes for production and service provision

Performance Technologies validates processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation demonstrates the ability of these processes to achieve planned results.

Performance Technologies has establish arrangements for these processes including, as applicable

- a) defined criteria for review and approval of the processes,
- b) approval of equipment and qualification of personnel,
- c) use of specific methods and procedures,
- d) records, and
- e) revalidation.

Processes that are not validated by monitoring or measurement are considered special processes. Special processes are monitored, and recorded by qualified operators. Special processes include qualification requirements specified for acceptance. Examples of these special processes include, but not limited to, the following:

- Wave soldering
- Hand Soldering
- Aqueous cleaning

### 7.5.3 Identification and traceability

Performance Technologies has documented processes for identifying product by suitable means throughout production realization. Performance Technologies identifies the product status with respect to monitoring and measurement requirements. Where traceability is required, the unique identification of product is controlled and recorded.

### 7.5.4 Customer property

Performance Technologies controls customer supplied product in the same manner as all other purchased material used in Performance Technologies products. Customer Supplied Product is defined as either product, material, or components provided by the customer. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained.

### 7.5.5 Preservation of product

Performance Technologies has established processes to preserve the conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

### Supporting Documentation

- Product Identification and Traceability Procedure
- Process Control Procedure
- Inspection and Test Status Procedure
- Control of Customer Supplied Product Procedure
- Material Handling, Storage, Packaging, Preservation, & Delivery Procedure



## 7.6 Control of Monitoring and Measuring Devices

Performance Technologies has determined the monitoring and measurement to be undertaken, and the monitoring and measurement devices needed to provide evidence of conformity of product to the determined requirements.

Performance Technologies has developed and maintains processes for the control, calibration, and maintenance of all monitoring and measurement equipment used to verify the compliance of products to specified requirements. Where necessary to ensure valid results, measuring equipment is to:

- be calibrated or verified at specified intervals, or prior to use, against equipment traceable to the National Institute of Standards and Technology (N.I.S.T.), where no such standards exist, the bases for calibration is documented;
- be adjusted or re-adjusted as necessary;
- be identified to enable the calibration status to be determined;
- be safeguarded from adjustments that would invalidate the measurement result;
- be protected from damage and deterioration during handling, maintenance and storage.

Performance Technologies equipment is calibrated according to an established process with records maintained. (reference Calibration Procedure) Measurement equipment is calibrated to manufacturer's specifications where applicable and traceable to the National Institute of Standards and Technology (N.I.S.T.). Records are maintained electronically within a database. (reference Control of Quality Records Procedure)

In addition Performance Technologies:

- assesses and records the validity of previous measuring results when inspection, measuring, or test equipment is found to be out of calibration, and;
- takes appropriate action on the equipment and any product affected;
- maintains records of calibration and verification of measuring equipment;
- All custom equipment and software is verified on a regular basis by the responsible department, as defined in the calibration record.

### Supporting Documentation

- Calibration Procedure
- Control of Quality Records Procedure



## 8.0 Measurement Analysis and Improvement

Performance Technologies plans and has implemented the monitoring, measurement, analysis and improvement of processes 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.

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

Performance Technologies planning, includes the applicable methods needed to accomplish monitoring, measurement, analysis and improvement of processes throughout the quality management system. Inspection and test results are used to determine if product conforms to specified requirements prior to release. Internal quality audits, inspection results and test results, through the use of corrective and preventive actions, are used to ensure conformity of the quality management system and provide feedback for continuous improvement.

### 8.2.1 Customer Satisfaction

Performance Technologies monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information may include:

- Input from the customer in the form of emails, phone or fax;
- responses to surveys.

Performance Technologies customer satisfaction team utilizes customer surveys, direct customer contact, customer returns and sales to determine if the customer is satisfied with the product or services provided. Customer surveys and customer returns are documented, reported and analyzed.

### Supporting Documentation

- Quality Control Inspection Procedure
- Test Procedure
- Statistical Process Control Procedure
- Service Procedure
- Internal Audit Procedure
- Corrective and Preventive Action Procedure
- Customer Satisfaction Procedure



### 8.2.2 Internal Quality Audits

Performance Technologies has developed an internal audit process to assess the quality management system. The internal audit process provides objective evidence that an evaluation has been performed to determine whether the quality management system is effectively implemented and maintained.

Internal audits are scheduled and performed at regular intervals by independent qualified auditors. The results of internal audits are documented and may include nonconformances and potential areas of improvement. Results are provided to the personnel having responsibility for the area under audit. Follow up audit activities occur as appropriate depending upon the severity of the nonconformance. Follow up activities include the verification of the reported actions and results of the effectiveness of the actions taken.

Managers of audited areas have the responsibility to ensure actions are taken to correct any nonconformances found by the audit team. Responsibilities, planning requirements, audit results and audit records are defined in the Internal Quality Audit Procedure.

#### Supporting Documentation

- Internal Quality Audit Procedure



### 8.2.3 Monitoring and Measurement of Processes

Performance Technologies has suitable methods for monitoring and, where applicable, the 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 are taken, as appropriate, to ensure conformity of the product.

Performance Technologies has developed systems that defines the measurement methods used to evaluate process performance. These methods include but not limited to:

- On-Time Delivery is a method to measure the shipping process;
- On-Time Delivery and Performance of vendors is a method to measure the purchasing process;
- SMT Line Analysis is a method to measure the setup and changeover process of the manufacturing SMT production line.

Records are documented and maintained of the measurements made to determine the effectiveness of processes.

### 8.2.4 Monitoring and Measurement of Product

Performance Technologies monitors and measures the characteristics of product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with planned arrangements (reference 7.1).

Evidence of conformity with the acceptance criteria is maintained. Records indicate the department representative authorizing the release of product (reference 4.2.4).

Product release and service delivery cannot proceed until all the planned arrangements (reference 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Performance Technologies has developed documented processes that ensures product requirements have been met. The processes that are used to ensure product requirements are:

- Receiving Inspection;
- Inprocess Inspection;
- Final Inspection; and
- Test

Records are documented and maintained to provide evidence of product acceptance and release.

### Supporting Documentation

- Quality Control Inspection Procedure
- Test Procedure
- Service Procedure
- Corrective and Preventive Action Procedure

- Control of Quality Records Procedure



### 8.3 Control of Nonconforming Product

Performance Technologies product is reviewed in accordance with documented processes. The organization deals with nonconforming product 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;
- by taking action to preclude its original intended use or application.

Performance Technologies has established and maintains documented processes to ensure that product that does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The documented processes define the controls, related responsibilities and authorities for dealing with nonconforming product. Root cause of nonconformities, subsequent actions taken, and any concessions obtained, are documented and maintained (reference 4.2.4). Once nonconforming product is corrected it is re-verified prior to use to demonstrate conformity to the original requirements. When nonconforming product is detected after delivery or use has started, the organization takes action appropriate to the effects, or potential effects, of the nonconformity.

#### Supporting Documentation

- Control of Nonconforming Product Procedure
- Control of Quality Records



#### 8.4 Analysis of Data

Performance Technologies has determined, collected and analyzed appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data provides information relating to:

- customer satisfaction (reference 8.2.1),
- conformity to product requirements (reference 7.2.1),
- characteristics and trends of processes and products including opportunities for preventive action, and
- suppliers.

Performance Technologies Quality Assurance and Technical Support Groups collect and analyze data to demonstrate the suitability and effectiveness of the quality system, and to evaluate where continual improvement of the quality system can be made.

The effectiveness of processes are monitored by reviewing inspection results, test results and customer return records. The results of monitoring these processes allows us to identify and correct problems using the corrective or preventive action process.

The following process characteristics are recorded and reported on:

- Manufacturing Performance
- SMT Line Operation
- On-Time Delivery
- Supplier Quality Performance
- Customer Satisfaction
- Customer Complaints
- Product Returns
- Training Effectiveness
- Effectiveness of Quality System

Supporting Documentation

- Statistical Process Control Procedure
- Customer Satisfaction Procedure
- Human Resource Procedure
- Servicing Procedure
- Purchasing Procedure



## 8.5 Improvement

Performance Technologies is committed to continually improve the effectiveness of the quality management system through the use of the Quality Policy, Quality Objectives, Quality Reports, Audit Results, Corrective and Preventive Actions, and Management Reviews.

Performance Technologies Quality Management System is operated in a way to provide continual improvement through:

- the statement of the quality policy,
- quality objectives defined by management as specific milestones to be achieved;
- internal audit results to determine where opportunities lie for improvement;
- data analysis used to reveal areas that may be subject to potential nonconformances;
- corrective and preventive actions to report and correct current or potential nonconformances, and;
- management reviews.

### Supporting Documentation

- Internal Quality Audit Procedure
- Corrective and Preventive Action Procedure
- Control of Quality Records Procedure



### 8.5.2 Corrective action

Performance Technologies has taken 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 has been established to define requirements for:

- reviewing nonconformities (including customer complaints);
- determining the causes of nonconformities;
- evaluating the need for actions to ensure that nonconformities do not recur;
- determining and implementing action needed;
- recording of the results of action taken (reference 4.2.4), and
- reviewing corrective action taken.

Performance Technologies has established a corrective action system to report, investigate and implement actions to correct and prevent the reoccurrence of nonconformities. The corrective action system is maintained through the use of an electronic database. Corrective actions are assigned to a responsible individual and tracked by number and completion date. Corrective actions investigate and document the root cause and actions to correct supplier, internal, and customer reported nonconformities. All corrective actions are reviewed for effectiveness with final approval provided by the Director of Quality.

### 8.5.3 Preventive action

Performance Technologies has take action taken to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems. Documented procedures have been established to define 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 (reference 4.2.4), and
- reviewing preventive action taken.

Performance Technologies has established a preventive action system to report, investigate and prevent nonconformities. The preventive action system emulates the corrective action system.

### Supporting Documentation

- Internal Quality Audit Procedure
- Corrective and Preventive Action Procedure
- Control of Quality Records Procedure