



Quality Manual

081A000126



1.0 Scope

PT is a global supplier of advanced network communications solutions to service provider, government, and OEM markets.

1.1 Purpose

The purpose of this Quality Manual is to define the Quality System in its entirety for Performance Technologies (PT) located at 140 Canal View Blvd, Rochester New York 14623.

1.2 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 PT locations in Rochester, New York, and San Diego, California. PT's facility in Kanata , Canada is listed as the exclusion to this manual.

1.3 Corporate Overview

Performance Technologies was formed in 1981 under the laws of the state of Delaware and maintains its corporate offices at 140 Canal View Blvd, Rochester New York 14623. 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 is now trademarked under the name PT.

PT develops 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. 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.

1.4 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.



1.5 Regulation

1.5.1 Control

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

1.5.2 Distribution

The Quality Manual is a controlled document. There may be hard copies created for reference, or temporary distribution, but the only controlled version is in electronic state and maintained in the database containing ISO Procedures and Work Instructions. 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 PT is prohibited.

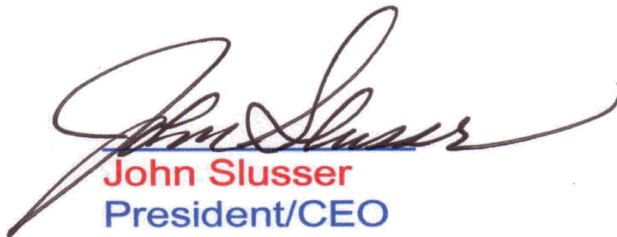
1.5.3 Revisions

Requests for changes to this Quality Manual can be submitted by any employee of PT. Each Request for Change must be submitted to PT's Director of Quality. Revisions to the Quality Manual are at the discretion of the Director of Quality and tracked by use of the Quality Manual Revision History table.

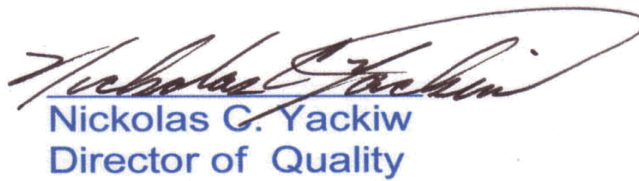


1.6 Approvals

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

Section	Document Name	Page
<i>1.0 General</i>		
1.1	Scope & Corporate Overview	1
1.5	Regulation	2
1.6	Approvals	3
1.7	Table of Contents	4
1.7	Table of Contents (cont)	5
1.7	Table of Contents (cont)	6
1.8	Revision Control	7
<i>2.0 Normative Reference</i>		
2.0	Normative Reference	8
<i>3.0 Terms and Definitions</i>		
3.0	Terms and Definitions	9
<i>4.0 Quality Management System</i>		
4.1	Quality Management Systems - General Requirements	10
4.1.1	Quality Management Systems - Flow Chart	11
4.2.1	Documentation Requirements - General Requirements	12
4.2.2	Documentation Requirements - Quality Manual	13
4.2.3	Documentation Requirements - Control of Documents	14
4.2.4	Documentation Requirements - Control of Records	15
<i>5.0 Management Responsibility</i>		
5.1	Management Commitment	16
5.2	Customer Focus	16
5.3	Quality Policy	16
5.4.1	Planning - Quality Objectives	17
5.4.2	Planning - Quality Management System	18
5.4.3	Planning - Manufacturing	18
5.4.4	Planning - New Design	18
5.4.5	Planning - Customer Contracts	19
5.5	Responsibility Authority and Communication	20
5.5.4	Organization Chart - Corporate Structure	21
5.5.4.1	Organization Chart - Operations & Administration	22
5.5.4.2	Organization Chart - Products & Technology	23
5.5.4.3	Organization Chart - Sales Marketing & Service	24
5.5.5	Responsibility Matrix	25
5.5.5	Responsibility Matrix (cont.)	26
5.6	Management Review	27



Table of Contents

Section	Document Name	Page
<i>6.0 Resource Management</i>		
6.1	Provision of Resources	28
6.2.1	Human Resources - General	28
6.2.2	Competence Awareness and Training	29
6.2.2	Competence Awareness and Training (cont)	30
6.3	Infrastructure	31
6.4	Work Environment	31
<i>7.0 Product Realization</i>		
7.1	Planning of Product Realization	32
7.1	Planning of Product Realization (cont)	33
7.2	Customer Related Processes - Contracts	34
7.2.3	Customer Communication - Servicing	35
7.3.1	Design and Development - Planning	36
7.3.2	Design and Development - Inputs	36
7.3.3	Design and Development - Outputs	37
7.3.4	Design and Development - Review	37
7.3.5	Design and Development Verification	38
7.3.6	Design and Development Validation	38
7.3.7	Control of Design and Development Changes	38
7.4.1	Purchasing - Purchasing Process	39
7.4.2	Purchasing - Purchasing Information	40
7.4.3	Purchasing - Verification of Purchased Product	41
7.5	Production and Service Provision	42
7.5.1	Control of Production and Service Processes (cont)	43
7.5.2	Production and Service Provision - Validation of Processes	44
7.5.3	Identification Traceability /Inspection and Test Status	45
7.5.3	Identification Traceability /Inspection and Test Status (cont)	46
7.5.4	Customer Property	47
7.5.5	Preservation of Product	48
7.6	Control of Monitoring and Measuring Devices	49
7.6	Control of Monitoring and Measuring Devices (cont)	50



Table of Contents

Section	Document Name	Page
<i>8.0 Measurement, Analysis and Improvement</i>		
8.1	Measurement Analysis and Improvement - General	51
8.2.1	Customer Satisfaction	51
8.2.2	Internal Quality Audits	52
8.2.3	Monitoring and Measurement of Processes	53
8.2.4	Monitoring and Measurement of Product	53
8.3	Control of Nonconforming Product	54
8.3	Control of Nonconforming Product (cont)	55
8.4	Analysis of Data	56
8.5.1	Continual Improvement	57
8.5.2	Corrective Action	57
8.5.3	Preventive Action	58



Quality Manual Revision History 081A0001XX

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
26	Major updates in multiple sections/pages due to: - Address Change - Organizational Changes - Flow Chart changes - Change to Contract Manufacturer	081A000126	080A003265	09/07/2012



2.0 Normative Reference

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

1. ISO 9001, Quality management systems - Requirements
2. ISO 9000:2005 "Quality management systems. Fundamentals and vocabulary"
3. ISO 9004:2009 "Managing for the sustained success of an organization. A quality management approach"
4. 082A300112: "Terms and Definitions Procedure"

The latest revision of these documents apply.



3.0 Terms and Definitions

For the purpose of this Quality Manual, PT references the terms and definitions listed in the ISO 9000:2005 "Quality management systems. Fundamentals and vocabulary" document. For the specific use of PT personnel, further terms and definitions are documented in the ISO Terms and Definitions Procedure.

The latest revision of these documents apply.

Supporting Documentation:

Terms and Definitions Procedure

ISO 9000:2005 "Quality management systems. Fundamentals and vocabulary"



4.1 General Requirements

PT is committed to adhering to the Quality Policy and establishing, implementing, and maintaining a Quality System.

Management commitment is demonstrated by communicating to the organization the importance of establishing the quality policy and quality objectives, conducting management reviews of the QMS, and ensuring the availability of necessary resources.

The QMS is made up of departments (shown in PT Quality Management Systems Flowchart) who have been given specific authority by Executive Management to implement and maintain the QMS. The QMS has been designed to ensure continual improvement and customer satisfaction through quality audits, management reviews, and other monitoring, measuring, and reporting on the effectiveness of processes and resource utilization. Necessary actions are identified and implemented to ensure that planned results are achieved.

Supporting Documentation:

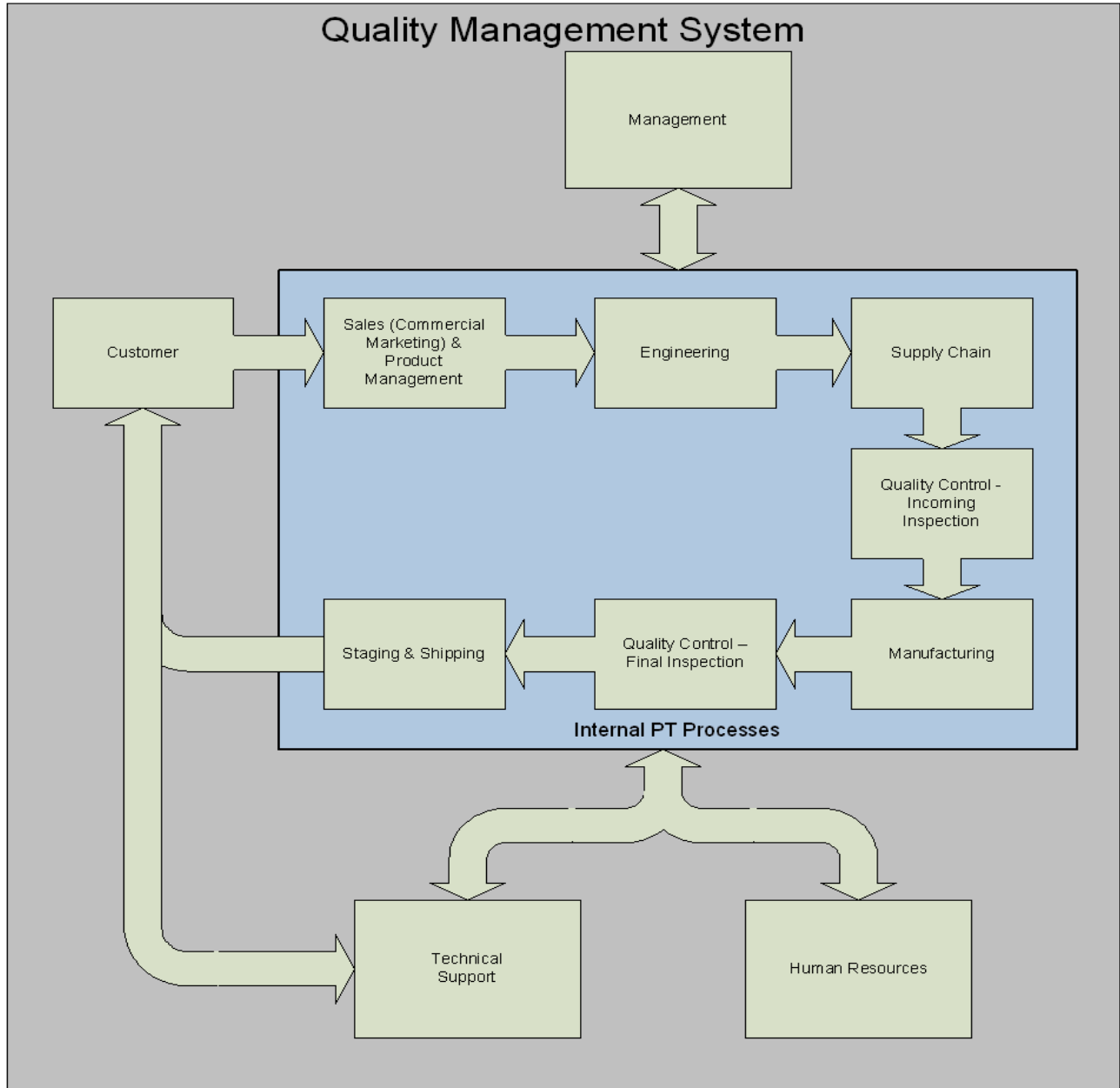
Management Responsibility Procedure

Quality Policy and Objectives

PT Quality Management Systems Flowchart



PT Quality Management Systems Flowchart



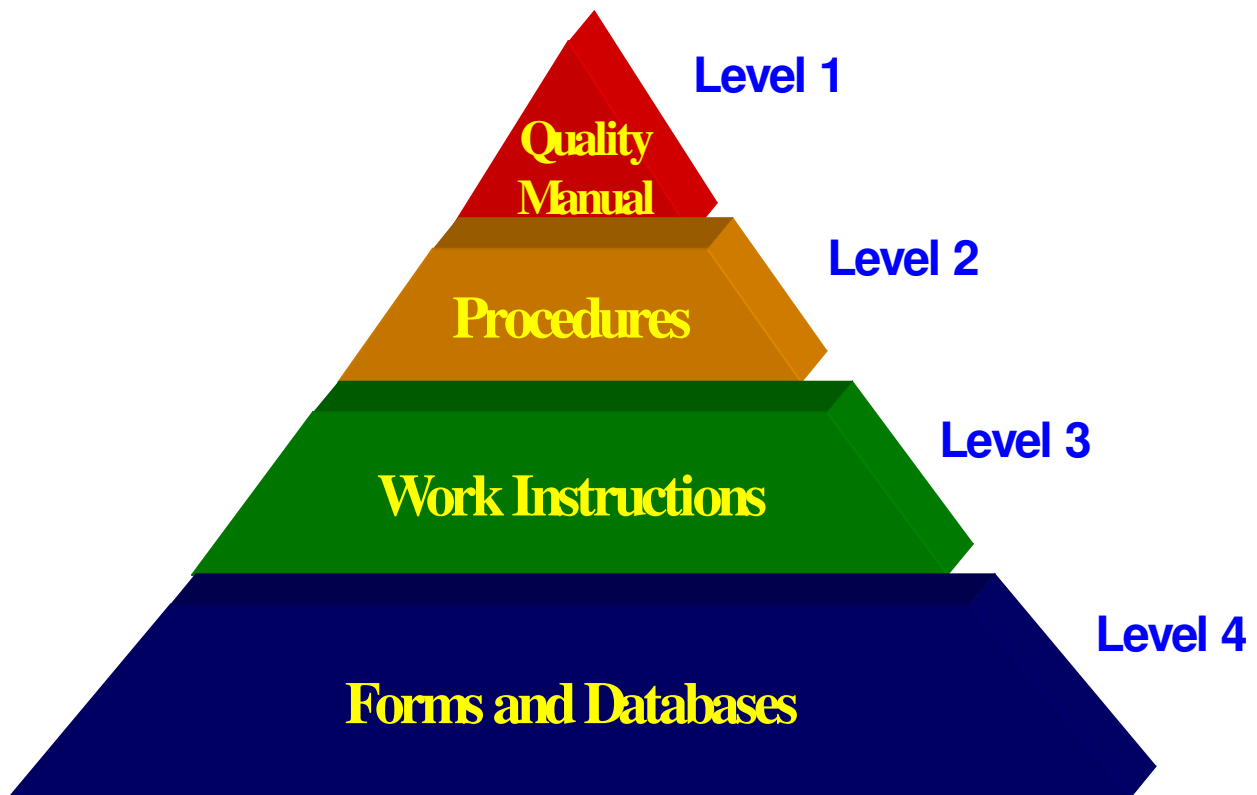


4.2 Documentation Requirements

4.2.1 General Requirements

PT has created **Quality Management System (QMS)** documentation which consists of the Quality Manual, Procedures, **Work Instructions**, and including relevant records that are required to support the effective operation of the organization's processes.

The **QMS** is comprised of four levels of documentation that are organized in a pyramidal fashion. The four levels of documentation include the Quality Manual, Procedures, **Work Instructions**, and quality system forms and Databases (Records).



Supporting Documentation:

Document and Data Control Procedure
Quality Management System Procedure



4.2 Documentation Requirements (cont.)

4.2.2 Quality Manual

PT has established this quality manual to define the Quality Management System. This quality manual contains:

- The scope of the quality system and justification for any exclusions;
- Description of quality management system processes and their interrelations;
- Reference to documented procedures (Supporting Documentation);

The quality management system documentation also defines criteria and methods needed to ensure that the operation and control of quality management system processes are effective. This usually includes assignment of responsibilities and allocation of resources for the process, instructions on how to carry out (or operate) the process, and definition of methods for monitoring and/or measuring the effectiveness of the process.

Supporting Documentation:

Document and Data Control Procedure
Control of Quality Records Procedure



4.2 Documentation Requirements (cont)

4.2.3 Control of Documents

PT has established and maintains procedures to control all documents and data related to the Quality Management System. This quality manual outlines how PT's Quality Management System controls documents and subsequent amendments.

4.2.3.1 Responsibility - Documentation Control is responsible for the control, distribution, and maintenance of documents supporting the Quality Management System through the use of electronic and hard copy data. Individual departments regulate and control their respective data and records.

4.2.3.2 Approval and Issue - Internally and externally generated documentation and data related to the requirements of the Quality Management System are reviewed and approved by authorized representatives prior to release. The documentation system, through the use of electronic data, allows the use of current revision documents and precludes the use of obsolete documents. Copies of documentation are distributed for either initial or change approval are marked as "**Unreleased**" or "**Preliminary**".

4.2.3.3 Document and Data Changes - Changes to documentation and data follow the Document Change Notice (DCN) procedure. Changes are reviewed and approved by the same authorized representatives that review and approve the initial release, unless otherwise noted and recorded. Representatives have access to any required documentation and information needed for use in making approval decisions.

Supporting Documentation:

Document and Data Control Procedure

Control of Quality Records Procedure



4.2 Documentation Requirements (cont.)

4.2.4 Control of Quality Records

PT has documented procedures for identification, collection, indexing, accessing, filing, storage, maintenance, and disposition of quality management system records.

4.2.4.1 Responsibility - Departments that create hard copy quality records are responsible for their control per documented procedures. Quality Records created by departments electronically are the responsibility of the Corporate Information Systems Group (CIS) to provide backup, storage and disposition of these records.

4.2.4.2 Control of Records - PT's quality management system details the identification, storage, protection, retrieval, retention and disposition of records, including pertinent subcontractor records, through documented procedures. Records are readily available and identifiable to the product or process involved and are protected against damage, loss, and deterioration. Retention times of Quality Records are documented within individual procedures. Quality Records are made available for customer review, when contractually stipulated.

Supporting Documentation:
Control of Quality Records Procedure



5.1 Management Commitment

Executive Management has committed to the development and implementation of the Quality Management System (QMS) and to continually improve its effectiveness by:

- Establishing a Quality Policy;
- Establishing quality objectives;
- Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- Conducting management reviews;
- Providing the necessary resources;

Department heads of Quality, Manufacturing, Design Engineering, Sales and Marketing shall support and assist management in meeting these objectives.

5.2 Customer Focus

Executive management ensures customer requirements are determined, understood and met throughout PT. This is accomplished through the use of customer related processes and the measurement and monitoring of the QMS. (See 7.2 and 8.2.1)

5.3 Quality Policy

The Quality Policy is reviewed on a periodic basis by executive management, to ensure that policy is still suitable and appropriate to the organization as well as continuing to comply with the quality management system. In addition, quality objectives are established that support the quality policy with the goal of continual improvement. Lastly, the quality policy is communicated within the organization through posting throughout the facility, part of new employee training process, and reinforcement through periodic review of the quality management system by all employees by their direct Supervisor.

It is the policy of PT 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
Quality Management System Procedure
Quality Policy and Objectives



5.4 Planning

5.4.1 Quality Objectives

PT's senior management has ensured that quality objectives, including those needed to meet the requirements for products (Ref 7.1) are established within specific departments in the company. Quality objectives are measurable and are consistent with the Quality Policy which:

- 5.4.1.1 Meets or exceeds customer expectations by effective communication and review of customer requirements.
- 5.4.1.2 Provide our customers with quality products and services, on time delivery, and at a reasonable cost.
- 5.4.1.3 Effectively manage our processes, products, and services to provide customer satisfaction.

Supporting Documentation:
Management Responsibility Procedure
Quality Policy and Objectives



5.4.2 Quality Management System Planning

PT quality planning is a structured method defining and documenting activities to ensure appropriate identification and implementation of quality requirements necessary for products and contracts.

5.4.3 Planning for Manufacturing

Quality planning is completed during manufacturing process development. Manufacturing/Test Engineering utilizes a checklist to assist in the identification of new or different manufacturing processes or Quality Management System requirements. Changes to the manufacturing process or Quality Management System are the responsibility of Manufacturing/Test Engineering and Quality groups respectively and are completed per documented procedures.

5.4.4 Planning for New Design (Design Engineering)

Quality Planning for new products is the responsibility of Design Engineering. They follow documented processes to work with Product Marketing and others to define customer and/or product requirements to develop a Project Plan. That Project Plan is the basis of their quality planning.

Supporting Documentation:

Management Responsibility Procedure
Manufacturing Engineering Procedure
Test Engineering Procedure
Design and Development Planning Procedure



5.4.5 Customer Contract (Standard Product)

Quality Planning for contracts is a result of the contract review process to ensure that the Customer's requirements are defined, understood, and that Performance Technologies has the capability to meet the requirements. The Sales Administration organization is responsible for the review of customer contracts.

Procedures are documented establishing the following review criteria:

5.4.5.1 Requirements are defined and documented;

5.4.5.2 Differences between the proposed contract and capability are addressed and resolved;

5.4.5.3 Contract amendments are reviewed and the changes are transferred the appropriate departments for implementation.

5.4.6 Customer Contract (Custom Product)

Sales Administration is responsible to review statements of requirement from customers for custom product. Statements of requirement are orders other than the standard Performance Technologies product where additional requirements are specified. Custom requirement implementation is completed per documented procedures.

Supporting Documentation:

Management Responsibility Procedure

Product Management Procedure

Sales Support Procedure



5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Responsibilities and authorities are documented in their respective procedures and work instructions. Department responsibilities are indicated in the **Responsibility Matrix** within the Quality Manual. Employee job descriptions have been created and are utilized to define the responsibility, authority and the interrelation of personnel affecting product quality. The organizational structure of the Quality Manual supports the job descriptions by providing a diagram to outline authorities and interrelation of personnel.

5.5.2 Management Representative

The President/CEO has assigned the responsibility and authority to the Director of Quality, as the Management Representative, to assure the requirements within this manual are established and maintained. The management representative shall have the responsibility to report on the performance of the QMS for review and as a basis for the improvement of the QMS. The Management Representative has the authority for approval of all procedures and work instructions within the QMS. All employees performing functions related to the requirements of this Quality Manual, as well as our customers, have access to the Management Representative.

5.5.3 Internal Communication

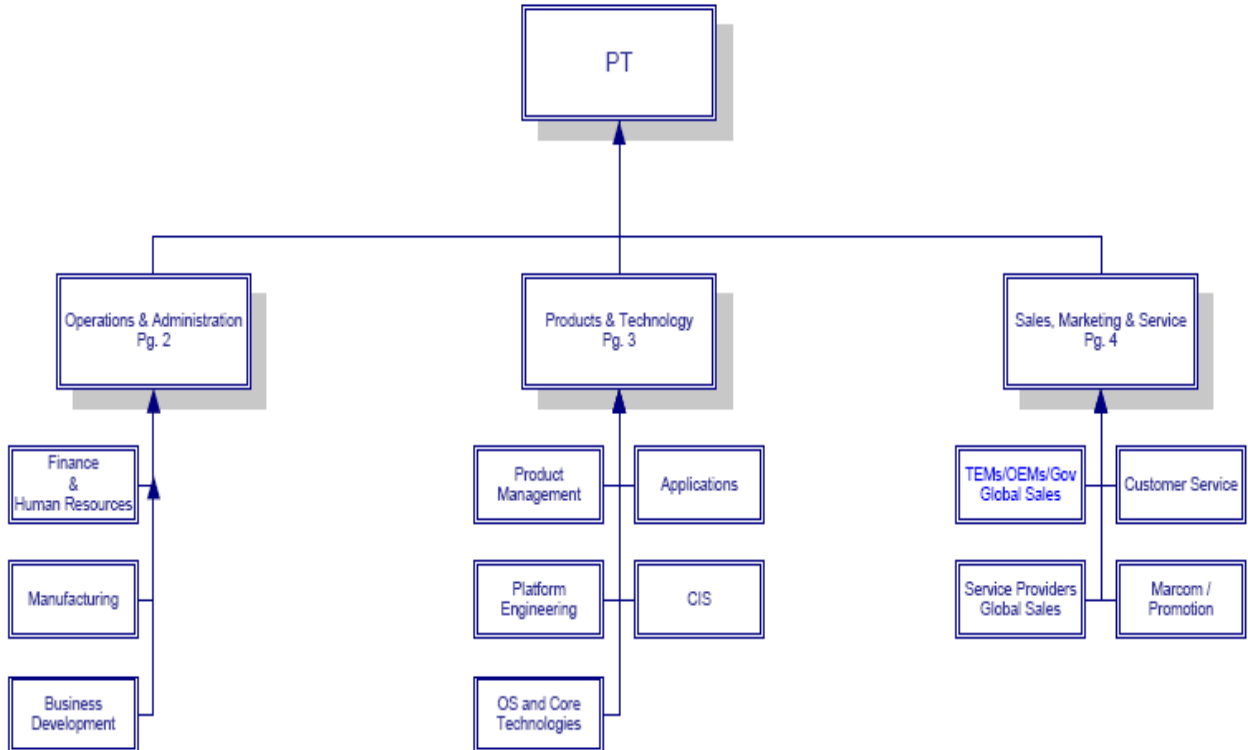
Executive Management ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the Quality Management System.

Records of internal communications by senior management are kept electronically in the Corporate Database and internal communications between departments are kept by each individual affected within each department

Supporting Documentation:
Management Responsibility Procedure

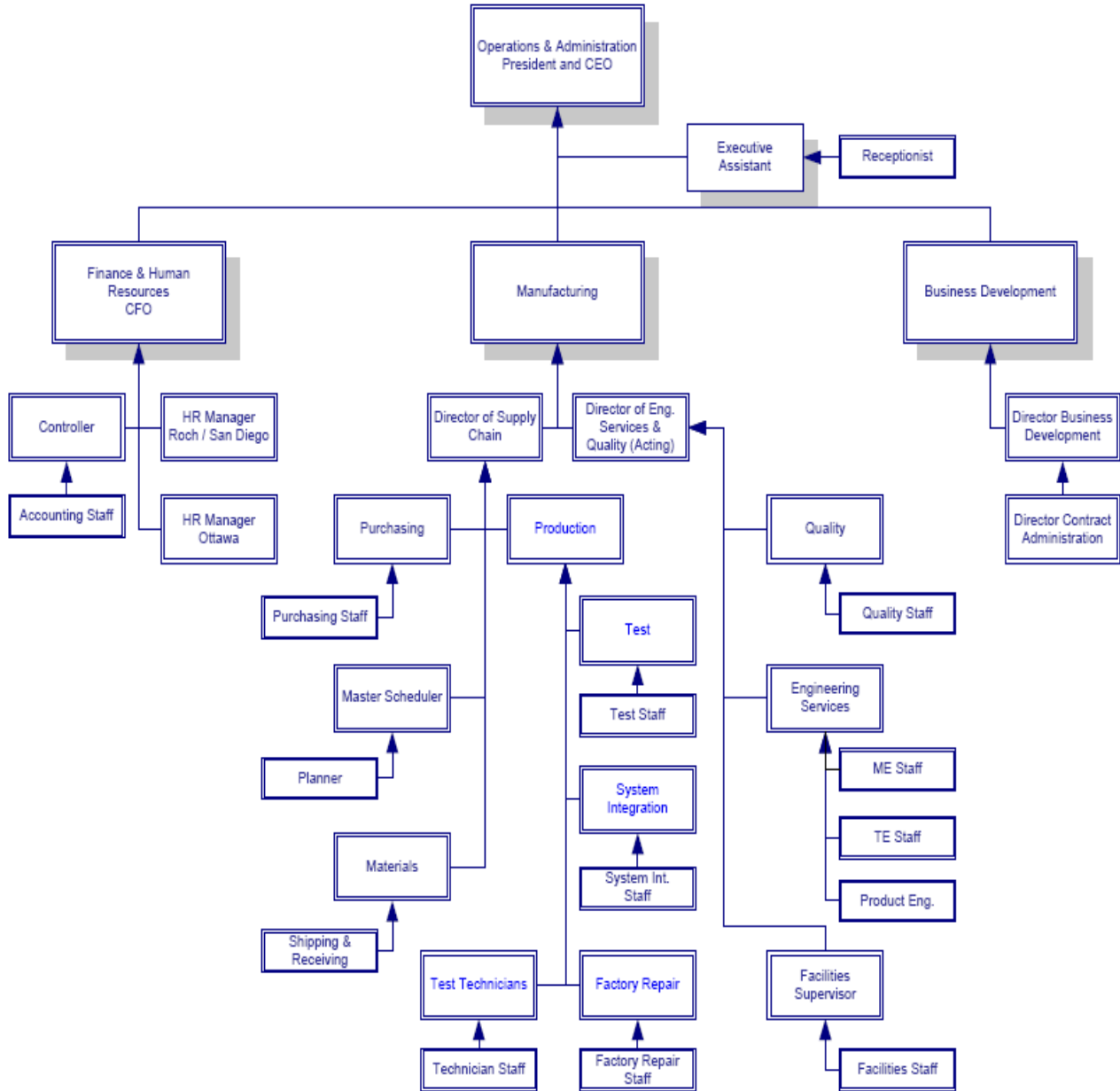


5.5.4 Organizational Structure



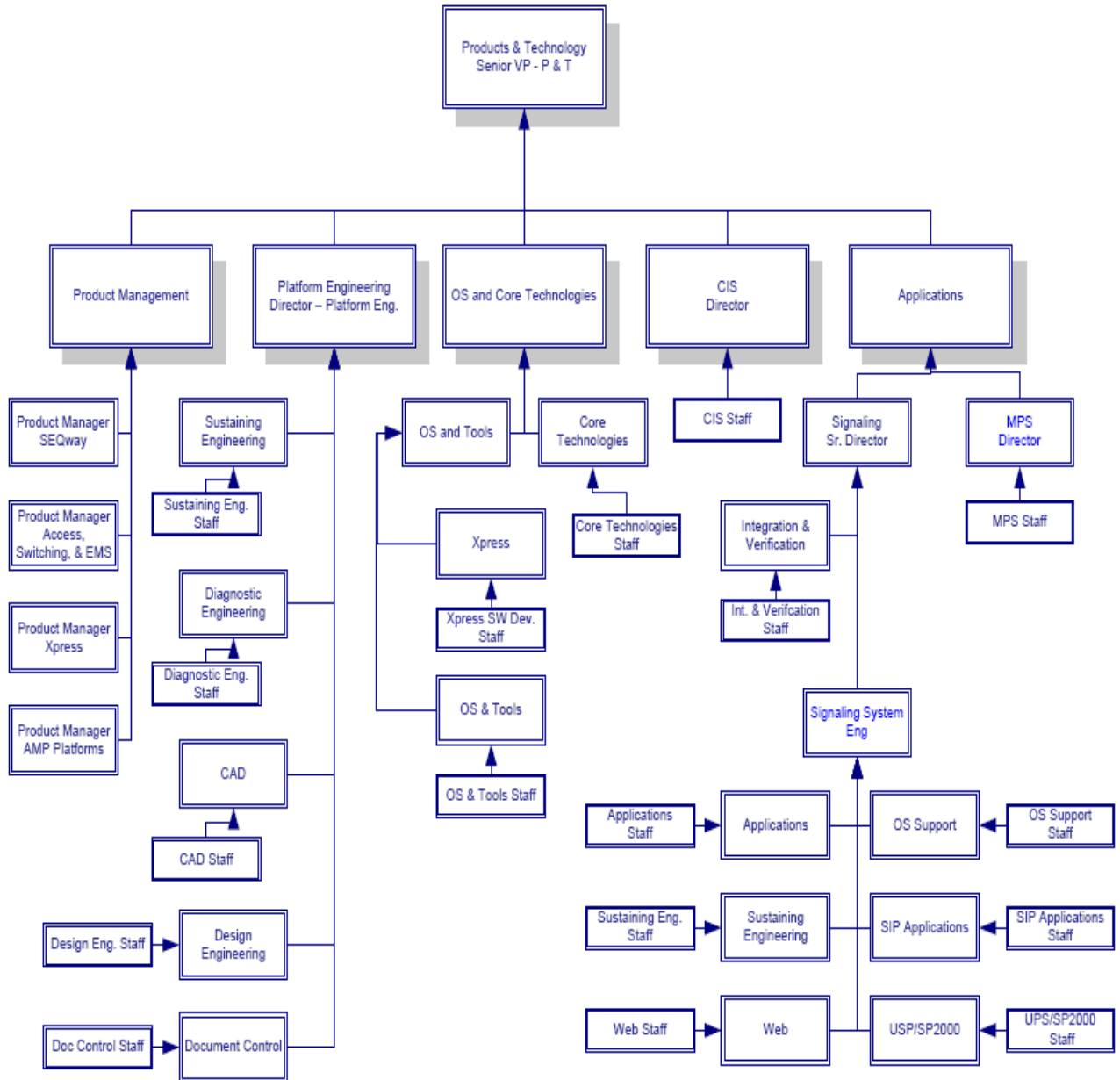


5.5.4.1 Operations & Administration



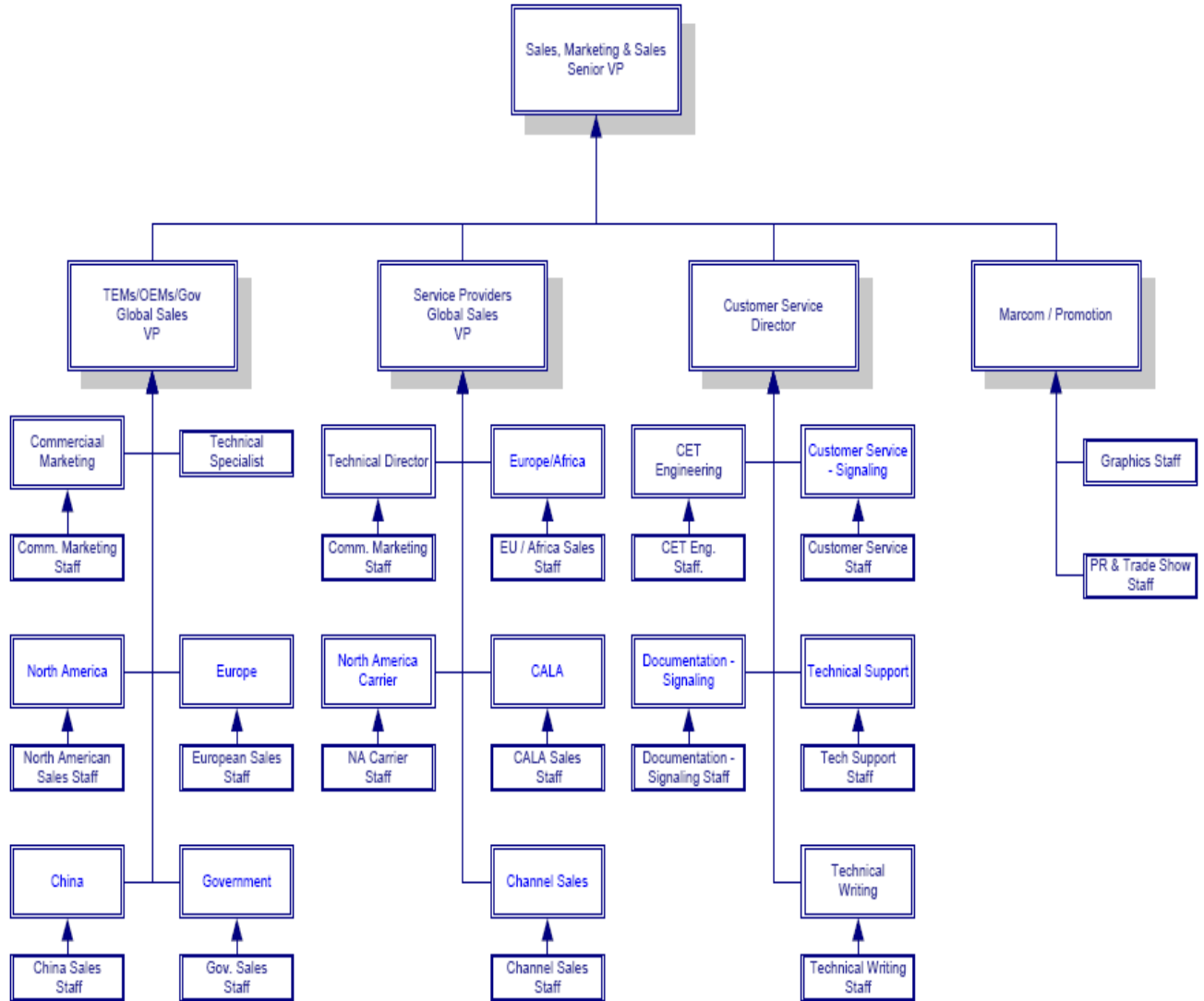


5.5.4 Products & Technology





5.5.4 Sales, Marketing & Service





5.5.5 Responsibility Matrix

Individual responsibilities are documented in their respective procedure or work instruction. In the following process audit matrix, PT's main processes are listed in the top section of columns. A single "X" in a box/cell indicates that there is an interaction between that section of the standard row, and the process identified in each column. A double "XX" denotes the process that has primary interaction for the marked section of the standard.

ISO 9001:2008 Standard Requirements		Sales (Commercial Marketing) & Product Management	Engineering	Supply Chain	QC – Incoming Inspection	Manufacturing	QC – Final Inspection	Staging & Shipping	Human Resources	Management	Technical Support
4.1	General Requirements	X	X	X	X	X	X	X	X	XX	X
4.2	General Documentation Requirements	X	X	X	X	X	X	X	X	XX	X
4.2.2	Quality Manual									XX	
4.2.3	Control of Documents	X	XX	X	X	X	X	X	X	X	X
4.2.4	Control of Records	X	X	X	X	X	X	X	X	XX	X
5.1	Management Commitment	X	X	X	X	X	X	X	X	XX	X
5.2	Customer Focus	XX	X	X	X	X	X	X	X	X	XX
5.3	Quality policy	X	X	X	X	X	X	X	X	XX	X
5.4.1	Quality Objectives (Planning)	X	X	X	X	X	X	X	X	XX	X
5.4.2	Quality Management System Planning	X	X	X	X	X	X	X	X	XX	X
5.5	Responsibility, Authority and Communication	X	X	X	X	X	X	X	X	XX	X
5.6	Management Review				X	X	X			XX	X
6.1	Provision of Resources	X	X	X	X	X	X	X	X	XX	X
6.2	Human Resources	X	X	X	X	X	X	X	XX	X	X
6.2.2	Competence, Awareness and Training	X	X	X	X	X	X	X	XX	X	X
6.3	Infrastructure	X	X	X	X	X	X	X	X	XX	X
6.4	Work environment	X	X	X	X	X	X	X	X	XX	X



5.5.5 Responsibility Matrix (cont.)

ISO 9001:2008 Standard Requirements		Sales (Commercial Marketing) & Product Management	Engineering	Supply Chain	QC – Incoming Inspection	Manufacturing	QC – Final Inspection	Staging & Shipping	Human Resources	Management	Technical Support
7.1	Planning of Product Realization	XX	X	X	X	X	X	X	X	X	X
7.2	Customer-Related Processes	XX	X	X	X	X	X	X	X	X	XX
7.3	Design and Development	X	XX	X	X	X	X	X	X	X	X
7.4	Purchasing	X	X	XX	X	X	X	X	X	X	X
7.5.1	Control of Production and Service	X	X	X	X	XX	X	X	X	X	X
7.5.2	Validation of Processes for Production and Service					XX				X	
7.5.3	Identification and Traceability	X	X	X	X	XX	X	X		X	X
7.5.4	Customer Property	X	X	X	X	X	X	X		X	XX
7.5.5	Preservation of Product	X	X	X	X	X	XX	X		X	
7.6	Control of Monitoring and Measuring Devices				X	X	XX				
8.1	General		X	X	X	X	XX			X	
8.2.1	Customer Satisfaction	X	X		X	X	X			X	XX
8.2.2	Internal Audit				X		XX			X	
8.2.3	Monitoring and Measurement of Processes		X	X	X	X	XX			X	X
8.2.4	Monitoring and Measurement of Product		X		X	XX	X			X	
8.3	Control of Nonconforming Product		X	X	X	X	XX				X
8.4	Analysis of Data	X	X	X	X	X	XX	X	X	X	X
8.5.1	Continual Improvement	X	X	X	X	X	XX	X	X	X	X
8.5.2	Corrective Action	X	X	X	X	X	XX	X	X	X	X
8.5.3	Preventive Action	X	X	X	X	X	XX	X	X	X	X



5.6.1 General

Management reviews are conducted at predetermined intervals to assess the suitability, adequacy and effectiveness of the Quality Management System (QMS). The reviews are necessary to assess the opportunities for improvement and the need for changes to the QMS, including the Quality Policy and quality objectives.

5.6.2 Review Input

The input to the management review includes:

- Internal and External Audit results;
- Customer feedback;
- Process performance and product conformity;
- Review of the Quality Policy;
- Status of Corrective and Preventive actions;
- Follow-up actions from previous management review;
- Quality Objectives and Improvement recommendations of the QMS.

5.6.3 Review Output

The results from the management review shall include decisions and actions that is related to:

- Improvement of the effectiveness of the QMS and its supporting processes;
- Improvement of product related to customer requirements;
- Resource requirements.

Supporting Documentation:

Management Responsibility Procedure
Quality Policy and Objectives
Servicing Procedure



6.1 Provision of Resources

PT's executive management is committed to provide adequate resources for the implementation and improvement of the quality system, and for addressing customer satisfaction.

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

6.2 Human Resources

6.2.1 General

Human Resources has been assigned the responsibility by Executive Management to ensure employees are competent based upon appropriate education, training, skills and experience. Human Resources is responsible to manage activities required to match personnel competence, experience and training to the organization's requirements. Employees are made aware of the importance of their activities, and how they contribute to achieving quality objectives.

Human Resources is responsible to schedule training, record the effectiveness of Training and maintain appropriate records. Training requirements shall include, but are not limited to, the qualifying of new employees, reassigned employees, employee retraining and new training.

Supporting Documentation:

Employee Training Procedure

Human Resources Procedure

Management Responsibility Procedure



6.2.2 Competence, Awareness and Training

6.2.2.1 Competence

Department managers are responsible for identifying competency requirements and training needs within their departments, and for establishing departmental training programs as required. Departmental training is primarily focused on increasing the skill level of employees in operating equipment and processes, conducting inspections, performing testing and using statistical techniques.

6.2.2.2 Awareness and Training Programs

Training requirements shall include, but are not limited to, the qualifying events of a new employee, reassigned employee, employee retraining and new product/equipment/skill training. Personnel performing specific tasks are qualified for the task on the basis of their education, training and/or experience. The following categories of company and departmental training and awareness programs for its employees are supported by Executive Management:

- a) **Quality Management System Orientation** - Each new employee participates in an orientation process provided by Human Resources. Initial training of the Quality Policy and QMS are performed and is scheduled from an employees orientation process. Human Resources is responsible to complete a "New Employee Check-Off List" for each new employee.
- b) **Safety Training** - Is an instruction in safe working practices, use of personal protective equipment, first aid, fire procedures, ESD prevention and others deemed appropriate. Training is provided by the Department Supervisor or Human Resources Department.
- c) **External Training** - External seminars, conferences, and courses. are provided to employees on as needed basis.
- d) **Skill Training** - Engineering, Production, and Quality Control departmental skills are often provided as on the job training.
- e) **Qualification Training** - On the job training shall be provided to personnel in any new position affecting product quality. Department supervisors shall establish operator qualification requirements as appropriate. Requirements for qualification shall address employee education, experience, training and demonstrated competency.

Supporting Documentation:
Employee Training Procedure
Human Resources Procedure



6.2.2 Competence, Awareness and Training (cont)

6.2.2.3 Training Effectiveness

Employee training effectiveness is determined through improvement in job performance and/or product quality. Training evaluations shall be conducted by the department supervisor to evaluate the effectiveness of training. Methods such as:

- Performance appraisals;
- Audits;
- Observation of the employee on the job;

6.2.2.4 Training Records

Employee training records shall be maintained by Human Resources and available to the employee and supervisor. Records of formal training, including supervisor conducted training, shall be maintained on file as part of the employee's **personnel** file.

Supporting Documentation:
Employee Training Procedure
Human Resources Procedure



6.3 Infrastructure

Executive Management has provided facilities, work spaces, tools, equipment, and associated utilities necessary to achieve conformity to product requirements and provide employee health and safety in the work place. Each department head is responsible for their employees and the maintenance of department work spaces, tools, and equipment where deemed appropriate.

6.4 Work Environment

Department managers are responsible to ensure facilities, work stations and associated production equipment are maintained in a state of order, cleanliness, and repair appropriate to the product(s) manufactured or to the service being provided. All work areas shall comply with established safety, regulatory and environmental standards and codes as deemed appropriate. The work environment conditions may include such factors as:

6.4.1 Human Factors

Department managers are responsible for ensuring suitable conditions in the company are maintained. Appropriate company policies are implemented mainly through training and corporate notifications.

6.4.2 Physical Factors

Facilities Manager, Manufacturing Engineering and Test Engineering are responsible for identifying those operations where environmental conditions could effect the performance of employees, equipment, or product, such as: heat, noise, humidity, etc.

6.4.3 Health and Safety

It is the responsibility of department managers to ensure health and safety is maintained in the work place. It is administrated by the Human Resource Department though the orientation process.

Supporting Documentation:
Employee Training Procedure
Facilities Procedure



7.1 Planning of Product Realization

Product realization plans are established in collaboration between Product Marketing, Engineering, Test Engineering, Manufacturing Engineering, and Quality groups. The plans are defined in various types of production documents, such as processes, production work orders, operator instructions and process validation reports. Product realization planning includes, as applicable

- Define quality objectives and requirements for the product;
- Establish processes, product documentation, and define resources specific to the product,
- Establish required verification, validation, monitoring, inspection and test activities specific to the product and criteria for product acceptance,
- Define records necessary to demonstrate process and product conformity.

7.1.1 Product Requirements

Product requirements for products are defined and communicated in drawings and specifications, contract documents, internal and external standards, product beta builds, workmanship standards, and applicable legal and regulatory requirements.

7.1.2 Quality Objectives

Quality Objectives are defined along with Product Requirements, but are also defined as part of PT's overall quality goals and objectives. PT specifies that products adhere to IPC Class 2 workmanship standards and utilizes internally developed Cosmetic and QMS documented procedures for 100 % testing, as well as appropriate inspection processes.

Supporting Documentation:

Quality Control Inspection Procedure

Test Engineering Procedure

Manufacturing Engineering Procedure

Product Management Procedure

Design and Development Planning Procedure



7.1.3 Custom Product Planning

A custom product is one that has special, **non-standard** product requirements specific to an individual customer. These requirements could be simply product branding, to customized hardware and/or software elements. Marketing and Sales will review these specifications before acceptance of the contract as defined in the Sales Support procedure. Custom products are manufactured, verified, and validated to those customer specifications and quality objectives specified in the documentation agreed upon between PT and the customer.

7.1.4 Standard Product Planning

Standard product planning is performed in accordance with documented procedures covered under the Product Realization process.

7.1.5 Product verification and validation planning

Procedures and supporting documentation have been developed and maintained for product verification and validation. Verification and validation testing is performed on materials and product prior to shipment to the customer. Nonconforming product/material is segregated from conforming product/material and handled in accordance with documented procedures.

7.1.6 Responsibilities

Design Engineering has the primary responsibility for the product verification documentation and process. The Design Engineering, Manufacturing Engineering, Test Engineering, and Quality groups are responsible for the development of product validation documentation. Verification and validation documentation is defined in various types of documents including, but not limited to; project plan, product assembly drawings and specifications, inspection checklists, and testing instructions.

7.1.7 Records

Test reports and/or checklists called out by the Project Plan are records that show evidence of the product's meeting expected requirements. Quality inspection and test records are records to show evidence validating proper operation of products before shipment to customers. These validation records are maintained in electronic databases which are analyzed, reported, and then distributed to management.

Supporting Documentation:

Quality Control Inspection Procedure
Test Engineering Procedure
Manufacturing Engineering Procedure
Product Management Procedure
Design and Development Planning Procedure



7.2 Customer Related Processes

PT has established and maintains procedures for the review of customer contracts and subsequent amendments. Commercial Marketing is responsible to review statements of requirement from customers in addition to standard product purchase orders. Statement of requirement documents are orders other than the standard PT product (Custom Product), where additional requirements are specified.

7.2.1 Determine the Requirements Related to the Product

Procedures and work instructions have been documented establishing the following review criteria:

7.2.1.1 Requirements specified by the customer are defined and documented by means of a Purchase Order, Request For Quote (RFQ), or contract.

7.2.1.2 Differences between the proposed contract and capability are addressed and resolved.

7.2.1.3 Determine any statutory and regulatory requirements.

7.2.2 Review of Requirements Related to the Product

Contracts are reviewed to ensure that the Customer's requirements are defined, understood, and that PT has the capability to meet those requirements.

7.2.2.1 The Commercial Marketing organization is responsible for the review of customer contracts and contract amendments. Any changes that are required are documented and transferred to the appropriate departments for implementation.

7.2.2.2 Records of contract reviews are maintained and review activities are coordinated with the customer as appropriate.

Supporting Documentation:

Sales Support Procedure

Product Management Procedure

Product Engineering Procedure



7.2.3 Customer Communication

The Marketing and Sales organization are the primary contact for ensuring that all customer requests for product information are satisfied and provide responses to customer inquiries about purchase orders, delivery dates and shipping requirements. Technical Support organization is the primary contact for resolving customer questions, complaints, product set-up, and problem solving.

7.2.4 Servicing

PT has developed and maintains procedures for performing, verifying and reporting servicing. This ensures that the repair and updating of returned product is performed and verified according to documented procedures and work instructions. The Technical Support Group and Sales, with the support of Quality Control, Engineering, and the Test Group, are responsible for servicing.

7.2.5 Technical Support

PT provides in house servicing of products through the operation of the Technical Support Group and the Factory Repair Group. The Technical Support Group is responsible to provide technical phone support, returned material authorizations (RMAs), customer training and internal technical support. The actual servicing of returned product for repairs and upgrades is provided in house by the Factory Repair Group.

Service records from the Technical Support Group and Factory Repair Group are maintained in electronic databases.

Supporting Documentation:

Sales Support Procedure
Factory Repair Procedure
Servicing Procedure



7.3 Design and Development

7.3.1 Design and Development Planning

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

- Definition of distinct stages that a project follows through its release process.
- Definition of the processes to be followed throughout the project's release phases, including review, verification and validation processes. and
- 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 to ensure effective communication and clear assignment of responsibilities.

Design and development planning is updated, as appropriate, as the project progresses.

7.3.2 Design and Development Inputs

Inputs relating to product requirements have been determined and records maintained (reference 4.2.4). PT has defined those inputs to include, but are not limited to:

- functional and performance requirements, determined from customer quotations and or proposals;
- applicable statutory and regulatory requirements as defined within the Project Plan.
- the review of previous designs or customer requirements and suggestions for product changes for applicable information where applicable;
- other requirements essential for design and development.

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

Design and Development Input Procedure



7.3 Design and Development

7.3.3 Design and Development Outputs

The outputs of PT's design and development are provided in a form that enables verification against the design and development input and is approved prior to release. The definition of PT's Design and development outputs include but are not limited to:

- meet the input requirements for design and development;
- provide appropriate information for purchasing, production and for service provision through documentation packages including Bills of Materials, assembly drawings, schematics and user manuals. Packages become available to manufacturing at time of release;
- contain or reference product acceptance criteria, defined by the documentation package as well as diagnostic code for testing and product verification, and
- specify the characteristics of the product that are essential for its safe and proper use as defined in product user manuals which includes setup, safety, configuration, and usage information.

7.3.4 Design and Development Review

PT's Design Engineering reviews each design project based on the design plan at suitable stages in accordance with planned arrangements (reference 7.3.1). Formal design reviews are documented through the use of the Design Review Checklist. These reviews are performed to:

- to evaluate the ability of the results of design and development to meet requirements;
- control and insight into the project's status for PTI Management, 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).

Supporting Documentation:

Hardware Design Procedure

Software Design Procedure

Design and Development Planning Procedure

Design and Development Output Procedure

Design and Development Review Procedure



7.3 Design and Development

7.3.5 Design and Development Verification

PT performs design verification in accordance with planned arrangements (reference 7.3.1) 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. Records of the results of the verification and any necessary actions are maintained (reference 4.2.4) by use of a verification checklist.

7.3.6 Design and Development Validation

PT design and development validation is performed in accordance with planned arrangements (reference 7.3.1) to demonstrate that the product design meets the requirements stated in the Project Plan and its intended application. Product validation is performed prior to wide-spread deployment of the product. Validation is typically performed as part of a Beta cycle at an actual customer site. Validation Test Plans and Validation Test Reports are kept to track the results of validation and any necessary actions are maintained (reference 4.2.4).

7.3.7 Control of Design and Development Changes

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 PT or requested by the customer, are reviewed and implemented by the Document Change Notice (DCN) process. PT's DCN process includes the review and assessment of the potential effects of these design changes on current as well as prior releases of the product being changed.

Supporting Documentation:

Hardware Design Procedure

Software Design Procedure

Design and Development Review Procedure

Document and Data Control Procedure



7.4 Purchasing

PT has established and maintains procedures to ensure that purchased material conforms to internal specifications and customer specified requirements, if applicable. Working relationships with each Supplier are established promoting communication to coordinate matters of quality including discrepancies and effective corrective action.

7.4.1 Purchasing Process

PT's purchasing process ensures that all Suppliers are evaluated prior to approval and entrance into electronic databases. Only approved Suppliers are used for purchase order placement. An electronic database of approved Suppliers is maintained by Purchasing and the Quality group. Another electronic database of manufacturer's part numbers tied to the approved Suppliers, is maintained by Design Engineering and Documentation Control. Purchase orders can only be placed for approved part numbers. Purchased material is verified by Receiving Inspection using documented procedures and documentation found within these electronic databases.

7.4.1.1 Responsibility

Purchasing, Design Engineering, and the Quality group are responsible for selecting Suppliers based on their ability to meet the specified requirements. The Quality group is responsible for the inspection of all product per documented procedures.

7.4.1.2 Evaluation of Suppliers

The evaluation of Suppliers is based upon any or all of the following: technical complexity of the products being considering purchasing from the Supplier, Supplier capability, product availability, total product cost, product quality, reputation, reference checks, quality management system audits, financial stability, and past and present performance history, if applicable. Records are maintained to measure each Supplier's rating during the evaluation process.

Supporting Documentation:
Purchasing Procedure



7.4.1.3 Selection of Suppliers

The selection of Suppliers is based upon their overall rating of the evaluation criteria, and final negotiation of terms and conditions.

7.4.1.4 Re-Evaluation of Suppliers

The re-evaluation of current Suppliers happens under one of two conditions; poor performance or in consideration of a change in product or service requested.

A current Supplier, who has been removed from PT's "Approved Vendor List", may be considered for re-approval after a re-evaluation per the original criteria

To re-evaluate a Supplier, if that Supplier is to be considered to supply goods or services in a capacity/capability beyond what they had been previously evaluated against, PT would follow the same evaluation process as for a new Supplier but based on the requirements of the new good or service.

7.4.2 Purchasing Information

The requirements for purchased material are clearly specified on the Purchase Order. These requirements include references to Part Number, revisions, and method of acceptance. Purchase orders are reviewed and verified prior to release.

Supporting Documentation:

Purchasing Procedure

Quality Control Inspection Procedure



7.4.3 Verification of Purchased Product

7.4.3.1 Receiving Inspection

Purchased material identified to be inspected upon receipt, is verified by Receiving Inspection using documented procedures. The sampling plan Mil-STD-105D, Inspection Level II, with a 1% AQL, for normal inspection shall be used unless otherwise noted. Receiving inspection records are maintained in an electronic database.

7.4.3.2 Subassembly Verification at Supplier's Premises

Subassembly purchase orders include requirements for product verification at the supplier's facility as determined by the Quality group and Purchasing.

7.4.3.3 Customer Verification of Purchased Product

When contractually required, the customer or customer representative is allowed to verify that product conforms to specified requirements. The verification can occur at our facility, our supplier's facility, or upon customer receipt. PT remains responsible for nonconforming product even though source inspection was completed without discrepancies.

Supporting Documentation:

Purchasing Procedure

Quality Control Inspection Procedure



7.5 Production and Service Provision

Product and process information, appropriate procedures and work instructions are established and are online for all personnel. Operation and production processes are monitored and controlled, and are validated when appropriate. Equipment used in production for assembly, for monitoring and measurement activities are maintained. Methods for product release and delivery are defined.

7.5.1 Control of Production and Service Processes

PT identifies and plans production and service processes that directly affect quality. These processes shall be verified using documented procedures and work instructions. Reference standards, software codes, engineering drawings and specifications, quality plans, and procedures are used to monitor and control product processes.

7.5.1.1 Equipment

PT has identified key process equipment, monitoring and measuring devices. A Preventive Maintenance program has been developed to maintain production equipment. Resources have been provided.

Supporting Documentation:

Quality Control Inspection Procedure
Inspection and Test Status Procedure
Servicing Procedure
Preventive Maintenance Procedure



7.5.1.2 Materials and Assemblies

PT controls the quality of purchased materials, internal sub-assemblies and assemblies by the use of documented procedures. The control of material and internal assemblies is accomplished by:

- a) Inspection and Testing;
- b) Providing for proper storage, segregated, handling and protection to maintain their suitability;
- c) Identification of material and assemblies for traceability;
- d) Control of Nonconforming product;
- e) Work Environment Control

7.5.1.3 Scheduling and Delivery

Product shall be properly stored that will protect the quality of the product after final inspection and test. Product shall be shipped to the customer in accordance with customer shipping information. The production scheduling process shall be order driven to maintain conformance to customer requirements.

7.5.1.4 Servicing

Servicing procedures have been created and maintained to ensure that contractual service agreements and product warranties are fulfilled. This is accomplished by direct contact with the customer to determine if all contractual agreement have been met and appropriate records are maintained.

Supporting Documentation:

Quality Control Inspection Procedure

Control of Nonconforming Product Procedure

Inspection and Test Status Procedure

Servicing Procedure

Product Identification and Traceability Procedure

Material Handling; Storage; Packaging; Preservation; & Delivery Procedure



7.5.2 Validation of Processes for Production and Service

PT documents and maintains procedures for all production, installation, and servicing processes which directly affect quality. PT does not identify any process within the Quality Management System that cannot be verified by subsequent monitoring or measurement. If, however, PT does identify a process where the resulting output cannot be subsequently monitored or measured, PT will validate those processes, which may include.

- a) Define the criteria PT will use to review and approve that process.
- b) Ensure that suitable equipment is used for that defined process.
- c) Ensure that the defined process(es) are compliant to documented procedures and work instructions.
- d) Define and implement process control techniques to monitor and control process parameters and product characteristics.
- e) Ensure that personnel are qualified to perform the defined process(es), or make arrangements to provide qualification training.
- f) Ensure adequate records are kept as proof of compliance of all activities related to the process validation.
- g) A review of a defined process will occur upon any changes to that process; i.e. a new product, different material, etc. That review shall be documented, and may lead to a revalidation of the process.

Supporting Documentation:
Manufacturing Engineering Procedure
Preventive Maintenance Procedure



7.5.3 Identification and Traceability, Inspection and Test Status

PT has established and maintains procedures for identification, traceability, inspection and test status of product. The Quality, Test, Test Engineering, and the Manufacturing Engineering groups are responsible for providing the necessary requirements for identification, traceability, inspection and test status of product.

Accept labels, reject labels, stamps and electronic data are used throughout manufacturing and servicing to indicate inspection or test status.

Manufacturing and the Quality groups are responsible for physical identification and database management.

- 7.5.3.1 All products throughout all phases of manufacturing, including individual components, are identified by part number.
- 7.5.3.2 Shop travelers are used to identify the product by part number, work order number, and quantity throughout the assembly process.
- 7.5.3.3 Electronic data entry steps and/or Inspection stamps are used to identify the inspector and inspection status of the physical assembly.
- 7.5.3.4 Part number/Date Code and barcoded serial number labels are placed on assemblies for individual identification and traceability.

Supporting Documentation:

Product Identification and Traceability Procedure
Quality Control Inspection Procedure
Inspection and Test Status Procedure



7.5.3 Identification and Traceability, Inspection and Test Status (cont)

7.5.3.5 Product serial numbers are entered into an electronic database enabling traceability and also providing test and inspection status information.

- a) Accept labels are used to indicate conformance of each lot by receiving inspection.
- b) Reject labels are used and applied to indicate the nonconformance of material rejected from inprocess or receiving inspection operations.
- c) Inspection stamps are used and applied to each product upon the completion of each in process inspection operation.
- d) Stamps are used and applied to indicate the conformance of **certain** test operations.
- e) Test and inspection status information is displayed by product serial number in an electronic database.

7.5.3.6 **Records**

Records for Identification and Traceability, Inspection and Test Status are maintained within electronic databases.

Supporting Documentation:

Product Identification and Traceability Procedure
Quality Control Inspection Procedure



7.5.4 Control of Customer Supplied Product

PT has developed and maintains procedures for the verification, storage and maintenance of customer supplied product. Supply Chain, Sales, Manufacturing, and Quality Group are responsible for controlling all customer supplied product.

PT controls customer supplied product in the same manner as internally purchased material. Customer Supplied Product is defined as either product, material, component, intellectual property, or personal data.

- 7.5.4.1 Customer supplied product is verified as conforming or nonconforming by incoming inspection using customer supplied specifications.
- 7.5.4.2 If customer supplied product is found to be nonconforming, lost, or damaged , a DMR (Discrepant Material Report) is completed and the customer is notified.
- 7.5.4.3 Customer supplied product is handled and stored in such a manner as to prevent damage. Special attention is paid to avoid damage from ESD (Electrostatic Discharge) and moisture sensitivity.
- 7.5.4.4 The verification process of PT does not absolve the customer from providing conforming product.

Supporting Documentation:

Material Handling; Storage; Packaging; Preservation; & Delivery Procedure
Factory Repair Procedure



7.5.5 Preservation of Product

PT has developed and maintains procedures for controlling the handling, storage, packaging, preservation, and delivery of material and products throughout the manufacturing cycle.

Its the responsibility of all departments to follow documented procedures for the handling, storage, packaging, preservation, and delivery of product. Procedures detail instructions for incoming material, stocked material, work in process, finished goods, and returned material and/or product. Where contractually specified, delivery procedural requirements may extend to receipt by customer.

Supporting Documentation:

Material Handling, Storage, Packaging, Preservation, & Delivery Procedure



7.6 Control of Monitoring and Measuring Devices

PT has developed and maintains procedures for the control, scheduled calibration, and maintenance of all inspection, measuring, and test equipment used to verify the compliance of products to specified requirements.

7.6.1 Responsibility

- 7.6.1.1 The Quality group is responsible for monitoring purchased and custom equipment calibration schedules and report on equipment due for calibration to the respective department supervisors.
- 7.6.1.2 Manufacturing Supervisors and Group Leaders are responsible for following documented procedures for calibration on equipment within their respective area.
- 7.6.1.3 The Quality group is responsible for determining calibration frequency and source.

Supporting Documentation:
Calibration Procedure



7.6 Control of Monitoring and Measuring Devices (cont)

7.6.4 Control Procedure

Equipment is calibrated according to calibration database records. Equipment as defined by the Quality Group requiring out source calibration, is calibrated to manufacture specifications by an outside calibration laboratory, using equipment traceable to the National Institute of Standards and Technology (N.I.S.T.). All custom equipment and software is verified on a regular basis by the responsible department, as defined in the calibration record.

- 7.6.4.1 All calibrated equipment is labeled and has an established frequency of calibration.
- 7.6.4.2 Equipment which is due for calibration is removed from use and isolated.
- 7.6.4.3 A record of all test equipment by name, make, serial number, location, and date of last calibration is maintained in a database by the Quality Group.
- 7.6.4.4 All new equipment requires initial calibration unless previously completed and documented by the manufacturer.
- 7.6.4.5 If equipment is found to be out of calibration, the validity of inspection, measuring, and test results are assessed and corrective action is initiated if necessary.
- 7.6.4.6 Calibration frequency is determined from the manufacturer's recommended interval and previous calibration records. The Quality Group has the ability to adjust calibration frequency based upon calibration results.
- 7.6.4.7 Test software and hardware is verified prior to use for functional accuracy and reverified at prescribed intervals.

Supporting Documentation:
Calibration Procedure



8.1 General

PT processes have controls at all stages to demonstrate the conformity of both the product and the Quality Management System (QMS), and to continually improve the QMS.

8.1.1 Statistical Techniques

PT identifies required statistical techniques and maintains procedures to implement statistical techniques to control and verify process capabilities and product characteristics.

8.1.1.1 Responsibility

Quality Assurance and Manufacturing Engineering are responsible to identify activities requiring control through statistical techniques.

8.1.1.2 Techniques

Documented procedures are maintained to apply statistical techniques for the control, verification and continuous improvement of process activities. Production performance, in-process inspection, and test results are recorded in electronic databases and tracked. Individual employee performance is tracked and recorded as part of production performance.

8.2 Monitoring and Measurement

Monitoring and measurements are made to determine customer satisfaction. This information is gathered from various sources and placed into reports for management to understand and take appropriate action when necessary.

8.2.1 Customer Satisfaction

PT monitors and measures customer satisfaction by gathering information from customer complaints (Corrective Action Requests), warranty returns, direct contact with the customer, customer call logs or other information obtained from the Commercial Marketing group.

Supporting Documentation:

Quality Control Inspection Procedure

Customer Satisfaction Procedure



8.2.2 Internal Quality Audits

PT has developed and maintains procedures for the planning, implementation and follow-up of internal quality audits.

Internal audits are used to demonstrate conformance and effectiveness of the Quality Management System (QMS).

8.2.2.1 Responsibility

Quality Assurance and the Internal Audit Team, appointed by the Director of Quality, are responsible for scheduling, conducting and recording audits of the quality management system. Internal audit results are provided to executive management for their review.

8.2.2.2 Audits

Internal Audits are compliance audits used by executive management to verify that quality activities comply with documented procedures and the QMS.

- a) Formally trained auditors conduct company audits. Internal auditors should have no direct responsibility to the department being audited.
- b) Audits are documented using an electronic database to record audit results and to detail nonconformities as appropriate. The database documents the compliance of quality activities to established procedures and also, that those procedures meet the applicable requirement of the ISO standard.
- c) Audit results are documented, indicating nonconformances, and reported to the appropriate department manager. The department manager is responsible to identify and implement actions required to correct nonconformances per documented procedures.
- d) Follow-up is then performed by the Internal Audit Team to determine the effectiveness of the corrective action.
- e) Records are maintained for all quality audits and audit preventive actions.
- f) Audit results are provided to executive management for their review.

Supporting Documentation:

Internal Quality Audit Procedure

Corrective and Preventive Action Procedure

Management Responsibility Procedure



8.2.3 Monitoring and Measurement of Processes

PT has identified measurement methods to evaluate process performance. These methods result in metrics. These metrics, which are the indicators of the effectiveness of the Quality Management System include internal quality audits, customer satisfaction and quality reports. These performance metrics may be an output of PT's internal processes, or from PT's Suppliers products/processes.

8.2.3.1 Internal audits are used to determine the conformance of the QMS. If any nonconformances are detected appropriate corrective actions are taken.

8.2.3.2 Customer satisfaction is measured by using any or all of the following:

- a) the number and overall percentage of warranty product returned to PT
- b) Customer complaints through Corrective Action Requests
- c) Direct contact with the customer,
- d) Analysis of customer call logs

8.2.3.3 Quality reports utilize inspection and test results to report on the effectiveness of the manufacturing process. Quality report informs management on:

- a) Manufacturing throughput;
- b) Product yield results;
- c) Customer on-time delivery;
- d) Customer product return rates;
- e) Inspection and Test yields;
- f) Receiving Inspection yields

8.2.4 Monitoring and Measurement of Product

Product characteristics are measured and monitored throughout the manufacturing process, to ensure the product meets established requirements. The inspection and test plans are documented by product part number or model number. Evidence of conformity with the acceptance criteria is maintained and electronic records identify inspection and test activities.

Supporting Documentation:

Quality Control Inspection Procedure

Test Group Procedure

Servicing Procedure

Internal Quality Audit Procedure



8.3 Control of Nonconforming Product

PT has developed and maintains documented procedures to control product determined as nonconforming. Nonconformances are marked and isolated to prevent unauthorized use or delivery. This process ensures nonconforming product is identified, documented, evaluated, segregated, and dispositioned to prevent unintentional use and shipment.

8.3.1 Responsibility

- 8.3.1.1 Quality Control and Test are responsible for the control of nonconformances.
- 8.3.1.2 The Material Review Board (MRB) has the responsibility and authority for the review and disposition of nonconforming product from the Discrepant Material Report (DMR). The MRB consists of authorized representatives from Quality Control and a cross-functional team comprised of individuals from within the manufacturing organization.
- 8.3.1.3 The Technical Support Group has the responsibility and authority for the control and disposition of nonconforming product returned from the customer.

Supporting Documentation:

Control of Nonconforming Product Procedure



8.3 Control of Nonconforming Product (cont)

8.3.2 Review and Disposition of Nonconforming Product

Nonconforming products are isolated until appropriate dispositions are determined and completed to prevent unintentional use.

8.3.2.1 Nonconformances are entered into the Discrepant Material Report (DMR) electronic database accompanied by a copy of the DMR Summary Form.

8.3.2.2 DMR's are reviewed and dispositioned by the MRB on a periodic basis per documented procedures.

8.3.2.3 The DMR electronic database serves as the record indicating nonconformance, disposition, and approvals.

8.3.2.4 DMR's dispositioned as repair or rework are reinspected per documented procedures prior to usage.

8.3.2.5 Product returned from the customer is identified by the Return Material Authorization number (RMA number) and reviewed by Customer Service.

8.3.2.6 RMA dispositions are recorded in an electronic database by Technical Support for analysis.

8.3.2.7 When contractually required, the proposed use of nonconforming product is recorded and communicated to the customer.

Supporting Documentation:

Control of Nonconforming Product Procedure



8.4 Analysis of Data

PT's Quality 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 effectiveness of the quality system can be made. Data and information recorded in quality records are compiled and analyzed monthly to determine trends in performance and effectiveness of the quality system and to identify areas of improvement.

The following categories of information and data are compiled, recorded and reported upon:

- **Manufacturing Performance** is recorded in electronic databases and reviewed for trends by Production Management and Quality.
- **On-time Delivery** is recorded in the Sales Order database. On-time deliveries is reported on monthly by Production Management.
- **Supplier Quality Performance** is recorded electronically in database files and evaluated for trends by Purchasing and Quality.
- **Customer Satisfaction** is recorded in the RMA and Customer call log databases and evaluated by the Technical Support and Quality Groups for any developing trends.
- **Customer Complaints** is recorded in the RMA and Customer call log databases and evaluated for trends by the Service Group and Quality.
- **Design Reviews** are held by Design Engineering to evaluate feedback data from verification testing to ensure that products meet their established requirements, and other benchmark data.
- **Effectiveness of the Quality Management System** is recorded in internal audit reports and is evaluated and reported to executive management during the management review meeting.

Supporting Documentation:

Service Procedure
Internal Quality Audit Procedure
Design and Development Review Procedure
Corrective and Preventive Action Procedure
Control of Nonconforming Product



8.5 Improvement

8.5.1 Continual Improvement

PT is committed to the continual improvement of the quality management system. This is accomplished through the use of the quality policy, quality objectives, analysis of quality data, audit results, corrective and preventive actions, and management reviews.

8.5.2 Corrective Action

PT has established a corrective action system to investigate and document the root cause and actions to correct supplier, internal, and customer reported 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.

The corrective actions taken will be appropriate to the effects of the nonconformities encountered. Documented procedures have 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 the effectiveness of the corrective action taken.

Supporting Documentation:

Corrective and Preventive Action Procedure

Management Responsibility Procedure



8.5.3 Preventive action

PT has established a preventive action system to report, investigate and prevent potential nonconformities. The preventive action system emulates the corrective action system. The preventive actions taken **will be** 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 **effectiveness of** the preventive action taken.

Supporting Documentation:

Corrective and Preventive Action Procedure
Internal Quality Audit Procedure