

## **Pikes Peak Test Labs, Inc.**

4750 Edison Avenue  
Colorado Springs, Colorado  
80915

# QUALITY ASSURANCE MANUAL

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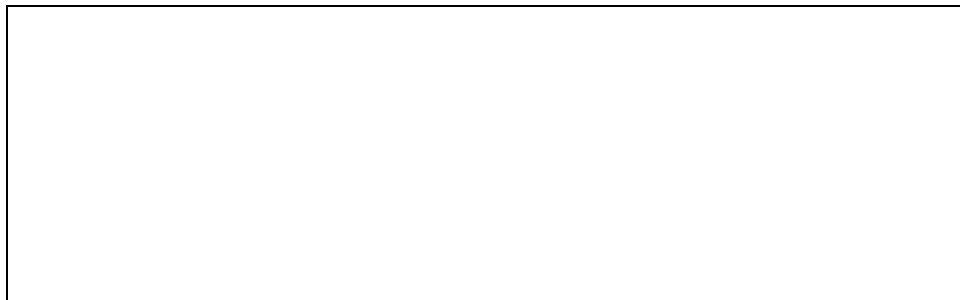
QAM

Revision S

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Originated By: L. Blondin

Approved By: \_\_\_\_\_ Title: \_\_\_\_\_ Date: \_\_\_\_\_



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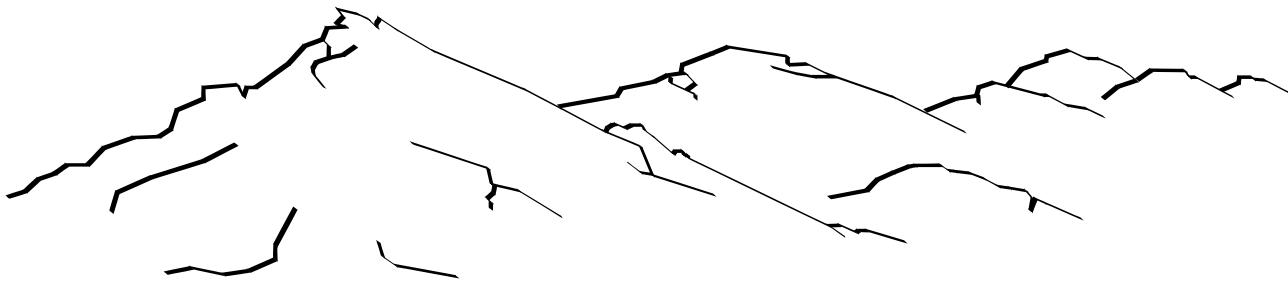
**Pikes Peak Test Labs, Inc.**

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## QUALITY ASSURANCE MANUAL REVISION RECORD

<u>REVISION</u>	<u>DESCRIPTION</u>	<u>DCR#</u>	<u>DATE</u>
N / C	Initial Release		09/20/88
A	Change reference from MIL-I-45662 to MIL-STD-45662.		05/22/90
B	Added MIL-STD-129 and TP-0002 to Parts / Instruments Handling and Packaging in the component paragraph.		08/31/92
C	Changes to internal audits, test stamps, frequency of calibration, and add government furnished material		09/17/93
D	Added MIL-I-45208 requirements per customer request in order to address all specification requirements		05/20/94
E	Added procedure for government furnished material		03/27/96
F	Deleted MIL-STD-45662. Added ANSI / NCSL Z540-1		07/23/96
G	Delete purchased parts disclaimer		08/15/96
H	Complete rewrite of manual		08/28/97
I	Changes to training section		02/11/98
J	Added reference documentation, training and retention, corrective action and follow up.		05/06/98
K	Review and update sections 2.0 and revise internal audit ck list form section 24.0		08/03/98
L	Revise Complete QAM		05/01/00
M	Revise to remove Form #s all sec's / Change Quality Policy		02/08/01
N	Add Sec 17		08/16/2002
O	Revise Org Chart, various sections	0782	07/11/2013
P	Revise to conform to ISO	0844	12/19/2014
Q	Revised to conform to ISO 9001:2015. Removed references to failure analysis services.	0945	3/9/16
R	Revised scope statement	1010	10/31/2016
S	Revised Sec. 4.4		08/22/2018



## **Pikes Peak Test Labs Inc.**

### *Quality Policy*

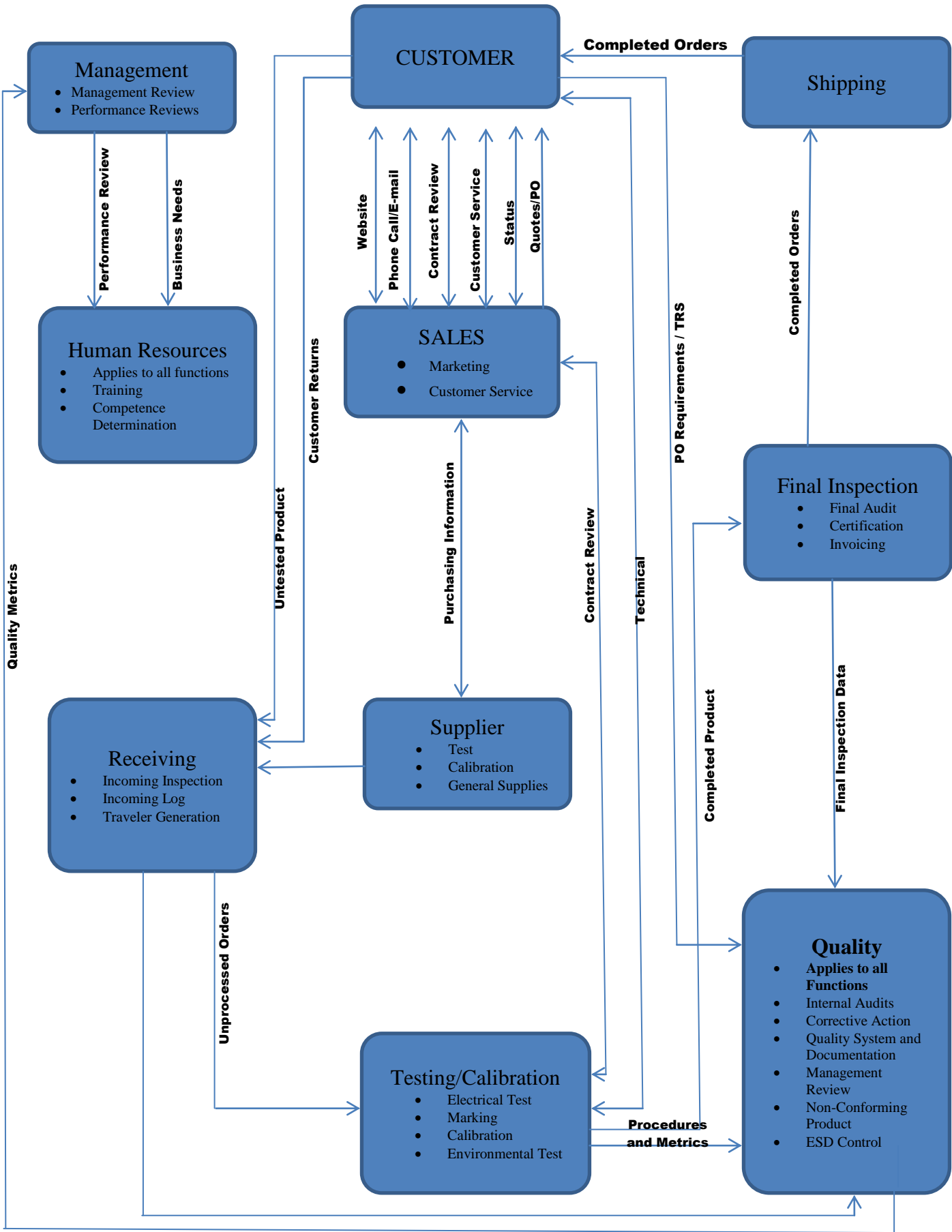
**Pikes Peak Test Labs Inc. is committed to achieving and maintaining a high quality service that will meet or exceed our customer's expectations. PPTLI is also committed to continuous quality improvement by employing individual and customer input through the quality system. Each individual employee is responsible and committed to a standard of excellence as outlined in the PPTLI quality system.**

**The management at PPTLI is responsible for providing the Training, Resources, Systems and Organizational support necessary to achieve company goals.**

*Bud Bennett*

**Bud Bennett, President**

# BUSINESS FLOWCHART



## INTRODUCTION AND SCOPE

Pikes Peak Test Labs, Inc. is a service oriented testing and calibration facility for military contractors, aerospace, and various local contractors.

Our Mission: To provide quality testing, evaluation, and certification of products and services, reliably and cost-effectively, and to meet and exceed our customer's requirements.

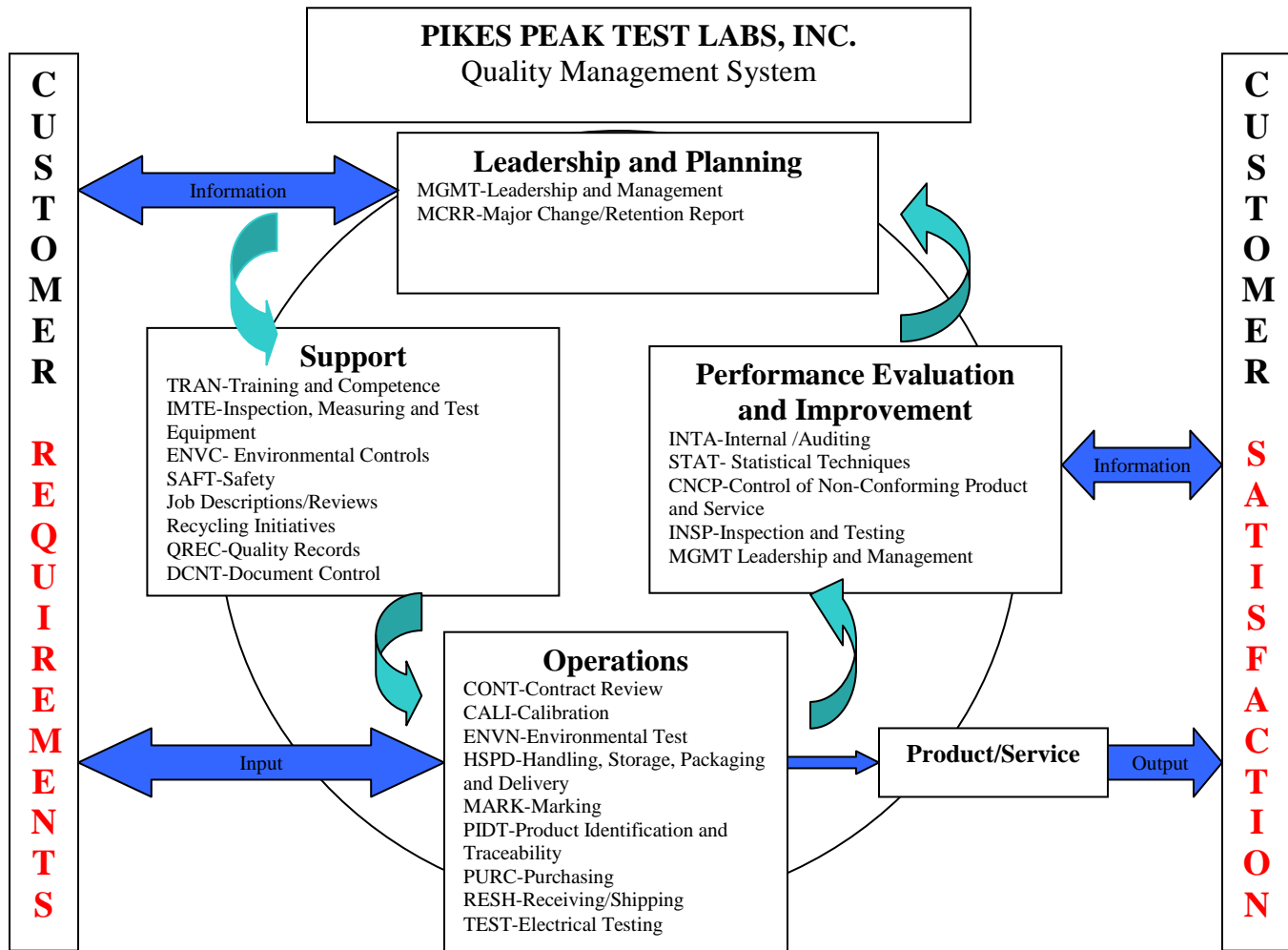
Pikes Peak Test Labs, Inc. employs a total quality strategy that empowers employees to use their talents and assume responsibility for PPTLI's success. This philosophy directs our efforts toward an incentive laden continuous improvement focus on customer satisfaction. All operations are performed within the requirements of this quality manual and ISO 9001:2015. The scope of quality management system is:

***Electronic component testing services including inspection, programming, marking and environmental testing. Mechanical and electronic calibration, adjustment and repair services for test and measurement equipment.***

The requirements of ISO 9001:2015 8.3, Design and development are not applicable as we do not design products. Failure analysis services are also offered; however PPTLI has determined this service will be an exception to our ISO 9001 quality management system since the scope of services offered in this department varies widely and is extremely dependent on customer needs.

In addition to the quality manual, each service area within the company also has an SOP, which more clearly defines local procedures.

A process approach is promoted during development, implementation and auditing of the quality management system, to enhance customer satisfaction by meeting or exceeding customer and other relevant interested party requirements.



## 1.0 QUALITY MANAGEMENT SYSTEM

### 1.1 Responsibilities and Authority:

Managers, supervisors and employees are obligated to work in accordance with the specific requirements of the documented quality system.

Management ensures that responsibilities and authorities are defined and communicated to all employees. Management is ultimately responsible for the quality of PPTLI's services and processes.

Though responsibilities and authorities ultimately reside with Management, they are delegated to competent personnel as necessary. All personnel who perform, manage, and/or verify work are responsible for the quality of products tested and services provided by PPTLI. All employees are responsible for complying with documented procedures and the direction of Management. All employees are authorized to identify and record problems relating to products, processes, and the quality system as a whole, and to provide suggestions for improvement or recommendations for solving problems by initiating appropriate actions. All employees are also responsible for cooperating fully with internal audits and audits performed by customers and the certified body.

Personnel are responsible for ensuring control over their activities and to complete work in a responsible and safe manner. All employees are responsible for maintaining the premises in a state of order, cleanliness, and repair consistent with processing needs. They are also responsible for identifying nonconforming product or service, stopping work as necessary, and controlling further processing until Management has been promptly notified and the problem has been corrected.

### 1.2 Quality Activities

All quality related activities are governed by procedures and written instructions. The quality system will aim to:

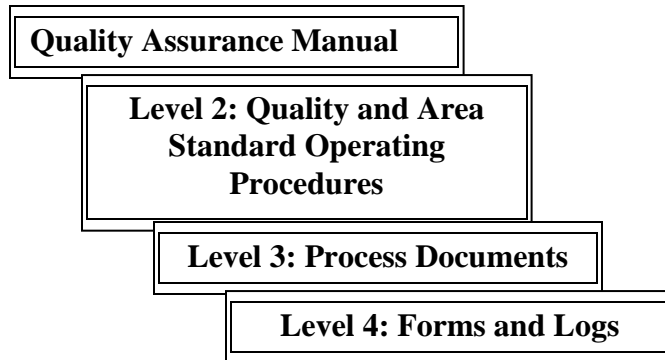
- Contribute to the overall quality of our services and workmanship, including meeting customer requirements.
- Establish and monitor current test capabilities.
- Maintain effective corrective and preventive action procedures for all areas of facility.
- Maintain effective management of measuring and test equipment.
- Maintain an effective self-audit system to ensure Quality System is continually checked and improved.
- To create a customer focused environment where our services are continually improved and our customers are confident that requirements are being fulfilled.
- Maintain an effective document control system.

Outsourced quality related activities are controlled as appropriate to the activity involved. Outsourced processing for customers' parts is controlled in accordance with the Purchasing and Receiving and Shipping procedures, the results of which are verified in accordance with the Receiving and Shipping procedure. Outsourced calibration service is controlled in accordance with the Calibration and Purchasing procedures; the results of which are verified in accordance with the Calibration procedure. Outsourced testing or inspection service is controlled in accordance with the Environmental Testing, Inspection and Testing, or Marking Area procedures as appropriate along with the Purchasing procedure. The results of outsourced test services are verified in accordance with the Receiving and Shipping procedure. Outsourced internal audits are controlled in accordance with the Internal Auditing and Purchasing procedures; the results of which are verified in accordance with the Internal Auditing procedure.

### 1.3 Quality management System Procedures:

Quality Management System Procedures will be documented to establish and maintain any processes affecting the quality of the service. To extent necessary, documented information is maintained to support the operation of the processes and documented information is retained to have confidence that the processes are being carried out as planned. Documentation hierarchy is demonstrated below:





All departures from documented Level 3 Procedures will be approved by the customer in writing or by the quality manager and must be documented on the traveler.

All records pertaining to the quality system will be kept in accordance with the Quality Records SOP.

## 2.0 LEADERSHIP AND PLANNING

### 2.1 PPTLI's Leadership Responsibility and Commitment

#### 2.1.1 Responsibility and Authority

The President has ultimate responsibility for the facility's services. He is also responsible for setting the facility's Quality Policy.

The Corporate Management Team monitors and advises the establishment and implementation of the quality system and reviews that quality system periodically for improvement opportunities to the QMS.

Departmental managers and supervisors are responsible for implementing the quality programs as set forth by the quality system and quality policy. All facility employees are responsible for the quality of services under their control.

Management is committed to the development and implementation of the quality management system and continually improving its effectiveness by:

- a) Taking accountability for the effectiveness of the QMS and by participating in QMS planning, internal audits and management reviews
- b) Communicating to the organization the importance of meeting customer and quality requirements through team meetings and by establishing continual improvement processes in the development of new processes and test methods.
- c) Establishing the quality policy and communicating it to the organization through procedures and training.
- d) Ensuring the quality policy and quality objectives are compatible with PPTLI's context and strategic direction
- e) Ensuring that quality objectives are established and met through oversight and sound management practices
- f) Ensuring the QMS requirements are integrated into PPTLI's business processes
- g) Promoting the use of the process approach and risk-based thinking
- h) Ensuring resources needed are available
- i) Communicating the importance of effective quality management and of conforming to QMS requirements
- j) Ensuring the QMS achieves its intended results
- k) Engaging, directing and supporting personnel to contribute to the effectiveness of the QMS
- l) Promoting improvement
- m) Supporting other management roles to demonstrate their leadership as it applies to their area of responsibility

#### 2.1.2 Commitment

Management also demonstrates a commitment to quality by conducting periodic management reviews of the QMS and its processes. Based on factual information regarding performance and other feedback from customers, and in consideration of future customer needs, Management allocates resources as necessary to ensure conformity of product and services, and to improve the QMS, its processes, and resulting services, in order to promote customer satisfaction

#### 2.1.3 Management Representative

The Quality Manager functions as the facility's management representative. He will have sufficient authority to ensure that the requirements of the QMS are maintained, including conformance to the requirements of ISO 9001, and ensuring that the processes are delivering their intended outputs. The management representative also ensures the promotion of customer focus throughout PPTLI. The management representative also ensures that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

In the absence of the management representative, a deputy may be appointed. The management representative reports to upper management on the status of corporate actions and can suggest any improvement areas.

#### 2.1.4 Management Structure

See the PPTLI Organizational Chart for current management structure.

#### 2.1.5 Management Job Responsibilities

See the Job Description chart in MGMT document for current management responsibilities.

#### 2.1.6 Planning

Management ensures that QMS planning occurs and is carried out in order to meet the requirements of our customers and other relevant interested parties as well as PPTLI's own internal requirements. QMS planning occurs at two levels: the process level and the system level.

Planning at the system level involves establishing the QMS processes and infrastructure necessary to meet general requirements of customers and other interested parties, focusing on the ability of the system to effectively and efficiently meet all requirements. This planning is conducted with a multidisciplinary approach, and takes into consideration facility and equipment plans, special process needs, handling, and value added use of floor space. This planning results in system-level processes and procedures that represent the planned arrangements described by QMS documentation.

The QMS Planning Tool ensures that Management identifies important considerations of the organization that are necessary to optimize the QMS' performance and thereby enhancing customer satisfaction. The QMS Planning Tool address the following:

- a) The purpose of the organization
- b) PPTLI's strategic direction
- c) Relevant external and internal issues impacting the performance of the QMS and PPTLI's services and the products resulting from the services provided,
- d) Recognition of interested parties and their requirements that have an effect or have the potential to affect PPTLI's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements,
- e) Opportunities to enhance desirable effects and contribute to achieving improvement,
- f) The organizational knowledge necessary to ensure conformity to requirements and for the operation of PPTLI's processes, and the means to maintain and upgrade organizational knowledge,
- g) A communications plan that includes internal and external communications that are relevant to the QMS, and,
- h) Reviewing product service operations to determine necessary process validations.

Risk-based thinking is applied to the QMS through the consideration of the internal and external issues and the requirements of relevant interested parties. The Risk Management Report identifies specific risks that need to be addressed to give assurance that the QMS can achieve its intended results, to prevent or reduce undesired effects, and achieve improvement. See the Leadership and Management procedure, and primary process procedures for on-going risk management.

In general, the quality plan for providing services and their resulting products is to process them in a manner consistent with the existing planned arrangements described by QMS procedures. Where new services containing significantly new or modified requirements are to be pursued, Management will ensure that quality planning is conducted, and that such planning is implemented and appropriately documented before promising to supply new or significantly modified services.

Where changes to the QMS are planned, due to opportunities that can enhance desirable effects, changes in technology or in the market, changes caused by relevant interested parties, changes to processes, procedures, or product and service requirements, introduction of new processes or

products or services, opportunities to achieve improvements, etc., Management will ensure that the integrity of the QMS is maintained to ensure conformity of product and service to requirements. The full impact of such changes will be determined, as appropriate. Any such changes will be verified and validated to ensure conformity to internal specifications, customer requirements and other relevant interested parties before implementation. Such QMS planning and change management is conducted during management review, or more frequently as circumstances dictate.

Planning at the process level focuses on providing products and services to ensure conformity of the products and service to applicable requirements according to customer and internal specifications and acceptance criteria, statutory and regulatory requirements, and any additional customer requirements. This planning is to establish processes and documentation specific to the products, services, and/or processes, and to identify specific resource requirements. This level of planning results in job travelers which identify required verifications to ensure conformity of the product, records demonstrating conformity, and methods for reacting when planned arrangements are not achieved.

#### 2.1.8 Associated Documents

- Quality SOP document MGMT

### **2.2 Major Change Retention Report**

#### 2.2.1 Responsibility and Authority

- The management representative has the responsibility and the authority to ensure this procedure is fulfilled and meets the requirements of the Quality System qualifying agency.

2.2.2 The management representative at PPTLI shall keep the qualifying agency (DLA) informed of major changes to certified processes and the quality system.

#### 2.2.3 Associated Documents

- Quality SOP document MCRR

## 3.0 SUPPORT

### 3.1 Resource Management

Management ensures that resource requirements are determined and met where they are needed to effectively operate and control QMS processes, to maintain and improve the QMS, and to achieve customer satisfaction by meeting their requirements.

Resource requirements include human resources (including personnel and training resources), infrastructure resources (including buildings, workspace, process equipment, operating supplies, measuring equipment, documentation, and supporting services and utilities), and work environment resources (including safety, ergonomic and human/physical aspects of work being performed).

Resource needs may be identified within any QMS process, or they may arise in connection with management reviews, corrective actions, risk mitigations, opportunities pursued, internal audits, employee observations, etc. Resource needs are fulfilled according to the Purchasing procedure and competent personnel are ensured through the Training and Competence procedure.

### 3.2 Training and Competence

#### 3.2.2 PURPOSE:

This section describes the method used to assure persons with appropriate qualifications fill all positions, which affect the quality of the product or service.

#### 3.2.3 RESPONSIBILITIES AND AUTHORITY:

Area managers and supervisors are responsible for ensuring personnel are properly trained and job duties fall within the individual's qualifications. Area managers and supervisors will also document all training records for personnel within their area of responsibility. Quality Assurance will maintain all master records pertaining to training. Quality Assurance is also responsible for reviewing training needs and preparing training plans.

#### 3.2.4 ACTIVITIES:

3.2.4.1 Training records are established and maintained for all personnel and include:

- Current job title
- Training relevant to performing that job
- Qualified process operators

3.2.4.2 Procedures identify operator prerequisites and identify PPTLI's training needs. Employee qualification is achieved by on the job training and supervisor approval. No employee will operate or perform a process unless qualified and signed off on the training log for the respective job task(s).

3.2.4.3 Trainers are qualified by a Trainer Evaluation Summary, which is filled out by QA. This form is used to evaluate potential trainers to train individuals for specified tasks. Potential trainers are qualified based on experience, education and character.

#### 3.2.5 ASSOCIATED DOCUMENTS:

- Quality document TRAN
- Personnel Training Qualification and Certification TRAN-001

### 3.3 Inspection, Measuring and Test Equipment

#### 3.3.1 PURPOSE:

This section describes how the inspection, measuring and test equipment used within PPTLI for the purpose of maintaining quality or testing materials, is controlled and calibrated.

### 3.3.2 RESPONSIBILITIES AND AUTHORITY:

Quality Assurance is responsible for the administration of this policy.

### 3.3.3 ACTIVITIES:

3.3.3.1 All equipment used by PPTLI to make measurements and to make acceptance / rejection decisions is maintained in a known state of calibration.

3.3.3.2 By procedure, all such equipment is checked on a regular basis against documented national standards of certification. Equipment found to be out of calibration is removed from use until corrected, re-tested and found acceptable. All calibration activity, including action taken in event of a non-conformance, is fully documented. Calibration records are held on file for the life of the equipment.

3.3.3.3 Equipment, which is either out of calibration or not operating correctly, will be deemed "Out of Service". Any "Out of Service" equipment will be either segregated from serviceable equipment or be tagged as such until calibration or repairs are completed.

3.3.3.4 All equipment will be handled in a non-damaging, safe and compliant manner to HSPD.

3.3.3.5 Government Furnished Equipment (GFE) will be handled according to the IMTE SOP.

### 3.3.4 ASSOCIATED DOCUMENTS:

- Quality document IMTE
- ANSI/NCSL Z-540

## 3.4 ENVIRONMENTAL CONTROLS

### 3.4.1 PURPOSE:

This section describes the environmental controls used to monitor the facility in critical areas.

### 3.4.2 RESPONSIBILITIES AND AUTHORITY:

The area managers/supervisors are responsible for ensuring environmental compliance in their respective areas. Quality Assurance is responsible for the overall administration of the environmental policy.

### 3.4.3 ACTIVITIES:

3.4.3.1 Environmental conditions in test areas shall be monitored. Environmental conditions for critical test areas are logged on the traveler. Test and/or calibration activities will cease if environmental conditions are outside of specified limits.

3.4.3.2 Environmental conditions for all MIL-STD Test methods will comply with the limits set forth in the respective standard.

3.4.3.3 Calibration environmental conditions shall be controlled and comply with ANSI/NCSL Z-540.

3.4.3.4 Each area supervisor shall collect the environmental data for that area and store for at least 10 years.

#### 3.4.4 ASSOCIATED DOCUMENTS:

- Quality document ENVC
- Calibration Operating procedure CALI
- Environmental Test Operating procedure ENVN
- Electrical Test Operating procedure TEST
- Marking Area Operating procedure MARK

### 3.5 Safety

#### 3.5.1 PURPOSE:

This section describes the safety measures applicable to all PPTLI employees.

#### 3.5.2 RESPONSIBILITIES AND AUTHORITY:

The area managers/supervisors are responsible for ensuring safety compliance in their respective areas.

#### 3.5.3 ACTIVITIES:

3.5.3.1 Safety conditions in every area shall be monitored.

3.5.3.2 Area SOP's shall each contain a safety section which addresses safety concerns particular to that area.

3.5.3.3 Safety incidents should be recorded on an "Incident Report Form" and submitted to the QA department.

#### 3.5.4 ASSOCIATED DOCUMENTS:

- Calibration Operating SOP CALI
- Environmental Test Operating SOP ENVN
- Electrical Test Operating SOP TEST
- Marking Area Operating SOP MARK

### 3.6 Job reviews/Descriptions

#### 3.6.1 PURPOSE

This section describes the employee performance review process and responsibilities

#### 3.6.2 RESPONSIBILITIES AND AUTHORITY

Area managers, supervisors of employees are responsible for documenting employee job descriptions and performance evaluations for each employee under their area of responsibility.

#### 3.6.3 ACTIVITIES

Every employee shall have periodic performance evaluations completed by their supervisor.

Job descriptions shall be included as part of the hiring process and the performance evaluations

#### 3.6.4 ASSOCIATED DOCUMENTS

- Calibration Operating SOP CALI

- Environmental Test Operating SOP ENVN
- Electrical Test Operating SOP TEST
- Marking Area Operating SOP MARK

### 3.7 Green Initiatives

#### 3.7.1 PURPOSE

This section describes the recycling initiatives to enhance corporate responsibility in the community.

#### 3.7.2 RESPONSIBILITIES AND AUTHORITY

All employees are responsible to use the recycle capabilities whenever possible.

#### 3.7.3 ACTIVITIES

3.7.3.1 Battery Recycling will be controlled through the calibration department. The department will provide a drop off area for all used batteries to be recycled. These batteries will then be disposed of or re-cycled in a safe and legal manner.

3.7.3.2 Waste mercury will be recycled through the calibration department. The department will provide a waste container for the spent mercury that can be shipped to a waste facility.

3.7.3.3 Aluminum cans will be recycled through a container that is placed in the break room. The operations manager will determine who is responsible for transporting the aluminum to a recycler.

3.7.3.4 Waste metals and electronics will be placed in bins provided by pre-determined waste administrators.

3.7.3.5 Other waste materials or chemicals shall be disposed of in a proper manner in keeping with all local and federal laws.

#### 3.7.4 ASSOCIATED DOCUMENTS

- Calibration Area SOP CALI
- Environmental Controls SOP ENVC

### 3.8 Document Control (Documented information that is maintained)

#### 3.8.1 RESPONSIBILITIES AND AUTHORITY:

Quality Assurance is responsible for administration of this policy.

#### 3.8.2 ACTIVITIES:

3.8.2.1 The Quality System is documented through the Quality Manual, Level 2 documents, Level 3 procedural documents, any referenced specs, and Forms and Logs.

3.8.2.2 Specified persons within the departments affected generate documents within the quality system. All necessary documentation will be available for any area of the facility where needed. Specifications or standards from an outside source (e.g. mil-STD) will be maintained in a controlled manner by Quality Assurance.

3.8.2.3 Any changes to quality related documents are reviewed by Quality Assurance and approved by the appropriate departmental manager or supervisor prior to being issued.



3.8.2.4 All document changes are recorded. A master list will show the current revisions of all quality related documents.

3.8.2.5 All software media generated by PPTLI or provided by the customer shall be maintained and controlled by Quality assurance.

3.8.2.6 Appropriate documents will be available in location where operations essential to the effective functioning of the quality system are performed.

3.8.2.7 Invalid or obsolete documents are promptly removed from all points of issue or use.

3.8.2.8 Obsolete documents that are stored electronically shall be maintained for a minimum of ten years.

3.8.2.9 The QA manger and company president are responsible for approving the QA manual. The QA manager and document authority are responsible for approving all other procedures. Forms are approved by the QA manager and the appropriate departmental representative.

### **3.9 Quality Records (Documented information that is retained)**

#### **3.9.1 RESPONSIBILITIES AND AUTHORITY:**

The Quality Assurance is responsible for administration of this policy.

#### **3.9.2 ACTIVITIES:**

3.9.2.1 All quality records are established, maintained and retained by PPTLI's Quality Assurance department and process areas. All quality records are held in confidence to ensure customer privacy.

3.9.2.2 Quality records will be maintained in a clean dry and secure location. Location will be noted in the corresponding area SOP.

3.9.2.3 Quality records will be kept for a minimum of ten years. Customers that require a longer storage time will be noted in record file.

#### **3.9.3 ASSOCIATED DOCUMENTS:**

- Quality Records QREC
- Document Control DCNT

## 4.0 OPERATIONS

### 4.1 Product ID and Traceability

#### 4.1.2 PURPOSE:

This section describes how services and materials are identified and controlled throughout the process.

#### 4.1.3 RESPONSIBILITIES AND AUTHORITY:

Department managers and Quality Assurance are responsible for administration of this policy.

#### 4.1.4 ACTIVITIES:

4.1.4.1 Customer product is tracked through a database system, using a control number and a traveler for tracking and identification purposes. The traveler also indicates the test and inspection status of the product. Any product that is "detached" from the traveler will be identified with a control number and labeled with the customer name.

4.1.4.2 All materials are accounted for at each work center. Any non-conforming product is clearly identified, segregated and recorded according to procedure.

4.1.4.3 The calibration area will conform to ANSI/NCSL Z540-1 standards with respect to traceability.

#### 4.1.5 ASSOCIATED DOCUMENTS:

- Quality SOP document PIDT

### 4.2 handling, Storage Packaging and Delivery

#### 4.2.1 PURPOSE:

This section describes the manner in which all materials and products are handled, stored, packaged and delivered.

#### 4.2.2 RESPONSIBILITIES AND AUTHORITY:

The operations manager and the area managers/supervisors are responsible for preserving the quality of received material and for the safe packaging (per customer or supplier spec) and delivery of all product, as well as the product within the process.

#### 4.2.3 ACTIVITIES:

4.2.3.1 Customer equipment and parts are carefully processed from receipt to delivery to minimize the chance of loss, physical or electrical damage. Any special handling requirements by the customer or supplier are documented and followed.

4.2.3.2 Procedures are implemented to prevent damage or other loss to materials or equipment by movement or storage within the facility. Delivery and packaging methods are taken into account upon delivery and agreed upon by the customer/supplier.

4.2.3.3 ESD sensitive materials are handled only at verified static-safe workstations by personnel trained in ESD handling. Workstations are equipped with grounded, static-free work surfaces and operators wear grounded wrist straps and conductive gowns while handling ESD sensitive devices. ESD sensitive devices are transported in static protective containers or bags.

4.2.3.4 Customer/supplier equipment or parts are stored in designated areas to minimize the chance of loss or damage.

4.2.3.5 All parts or equipment are packaged with protective material. Material and contents determine the type of packaging used.

4.2.3.6 Customer/supplier parts or equipment may be delivered by one of the following:

- An approved common carrier
- Any method specified by the customer
- PPTLI delivery vehicle
- Customer pick-up

4.2.4 ASSOCIATED DOCUMENTS:

- Quality Document HSPD
- ESD Policies and Procedures HSPD-001

### 4.3 Purchasing

4.3.1 PURPOSE:

This section covers the purchasing process for anything affecting customer product, including products and services.

4.3.2 RESPONSIBILITIES AND AUTHORITY:

Purchasing, Quality and the requesting party are responsible for the quality of the product purchased.

4.3.3 ACTIVITIES:

4.3.3.1 Product must conform to customer specifications. All supplier product or services must be approved by Q.A. through the use of an approved supplier list or the customer. Purchasing, marketing and quality will perform supplier qualification for purchased products or calibration services. Suppliers are formally approved according to documented procedure. Quality Assurance is responsible for maintaining supplier audit records and issuing an approved supplier list.

4.3.3.2 PPTLI will verify purchased products and services upon receipt against the order or contract.

4.3.3.3 All purchase order requests for calibration of customers measuring and test equipment must specify compliance to customer's quality standard and specify that a certificate of calibration is required.

4.3.3.4 Any purchase order requests for items affecting the quality of the workmanship must also be accompanied by a certificate of compliance to a stated quality standard, and must meet any standards set forth by the intended process specifications or standards.

4.3.4 ASSOCIATED DOCUMENTS:

- Quality document PURC
- Quality document RESH

### 4.4 Contract Review

4.4.1 PURPOSE:

This section describes the method used by PPTLI for the review and verification of customer contracts for testing, including the availability of equipment and PPTLI's capacity to meet the requirement.

4.4.2 RESPONSIBILITIES AND AUTHORITY:

Sales personnel shall be responsible to quote only those services that PPTLI or its subcontractors are capable and qualified to perform. Quotes shall not be issued nor Purchase Orders accepted that do not conform to any service capabilities of PPTLI or its subcontractors.

#### 4.4.3 ACTIVITIES:

4.4.3.1. Customer requirements are compared to actual departmental capabilities such as:

- Available equipment
- Packaging
- Test software
- Test fixtures
- Equipment capability
- Trained personnel
- Availability of specified parts

4.4.3.2 The Sales department shall be familiar with all standard non-technical services to ensure fulfillment of all customer contract order requirements.

4.4.3.3 For technical services beyond the capability of the Sales personnel (such as test software, for example), Sales shall ensure the appropriate engineer or technician reviews the requirements and verifies PPTLI ability to meet those requirements before a quote is issued to the customer for that service.

4.4.3.4 Customer changes to the original purchase agreement are reviewed as above and changes are documented on or as an amendment to the traveler and communicated to the personnel responsible for performing the work.

#### 4.4.4 ASSOCIATED DOCUMENTS:

- Quality SOP document CONT

### 4.5 Area Requirements

#### 4.5.1 PURPOSE:

This section documents the major requirements for the testing and service departmental areas within PPTLI to maintain a well-functioning system in compliance with the quality system. These areas include the following:

- ❖ CALIBRATION
- ❖ ENVIRONMENTAL
- ❖ MARKING and PACKAGING
- ❖ ELECTRICAL TEST
- ❖ RECEIVING AND SHIPPING

#### 4.5.2 RESPONSIBILITIES AND AUTHORITY:

Area managers/supervisors are responsible for the compliance to the requirements outlined in each area's Standard Operating Procedure. Area managers/supervisors are also responsible for verification of all processes affecting product quality within their respective areas.

#### 4.5.3 ACTIVITIES:

The Standard operating Procedure shall govern major quality requirement elements including (when applicable) but not limited to:

- Procedures of major functions
- Safety
- Handling of parts/tools
- Packaging
- Responsibilities of operators/technicians
- Equipment
- Environmental controls
- Storage
- Documentation
- Flowchart for processes in area

#### 4.5.4 ASSOCIATED DOCUMENTS:

- TEST Area SOP
- CALI Area SOP
- ENVN Area SOP
- MARK Area SOP
- RESH Area SOP

### 4.6 Inspection and Test Status

#### 4.6.1 PURPOSE:

This section describes the method used to indicate the inspection and test status of supplied services or work in process.

#### 4.6.2 RESPONSIBILITIES AND AUTHORITY:

Operators and area managers are responsible for ensuring the inspection and test status identification of work in process.

#### 4.6.3 ACTIVITIES:

4.6.3.1 Each employee is responsible for the quality and inspection of their own work, and to provide the required inspection status. The identification of inspection and test status is maintained to give evidence of product status. Any non-conforming product is physically segregated and tagged to prevent inadvertent integration with good product.

4.6.3.2 Inspection and test status is documented through the use of travelers, non-conforming reports, physical location of product, calibration records, and the "Prime" software system.

#### 4.6.4 ASSOCIATED DOCUMENTS:

- Quality document INTS

## 5.0 PERFORMANCE EVALUATION AND IMPROVEMENT

### 5.1 Internal Audit System

#### 5.1.1 PURPOSE:

This document describes the system by which PPTLI verifies the overall quality performance and corrective actions of the company in order to assure customer satisfaction.

#### 5.1.2 RESPONSIBILITIES AND AUTHORITY:

Quality Assurance is responsible for planning and controlling the internal audit system. Qualified auditors are given the responsibility to audit areas of the facility. Area Managers/supervisors are responsible for implementing agreed upon corrective actions.

#### 5.1.3 ACTIVITIES

5.1.3.1 Every element of the documented quality system undergoes a complete audit a minimum of once per year. These audits are conducted in accordance with documented procedures with an objective of ensuring continued effectiveness of the quality system. Audits will be performed by qualified auditors who, when possible, are independent of the area being audited.

5.1.3.2 Results of internal audits are recorded and any non-compliance is written up as a corrective action and followed up by the area manager/supervisor of the audited area.

5.1.3.3 Audit results are reviewed during management review and evaluated for effectiveness.

#### 5.1.4 ASSOCIATED DOCUMENTS:

- Quality document INTA

### 5.2 Statistical Techniques

#### 5.2.1 PURPOSE:

This section describes the system used to select, implement and use statistical techniques to monitor the effectiveness of the quality system.

#### 5.2.2 RESPONSIBILITIES AND AUTHORITY:

5.2.2.1 Quality Assurance and the area managers/supervisors will identify the need for statistical techniques to be employed in their area of responsibility. The information generated from these reports will be utilized to effectively enhance the quality of services in the respective area.

#### 5.2.3 ACTIVITIES:

Key process characteristics are identified by the area managers/supervisors in conjunction with the QA department. These characteristics identify key attributes of the area that directly related to customer satisfaction. Area managers/supervisors generate the appropriate reports. This information is utilized to make adjustments to the areas in order to better meet customer requirements.

5.2.3.2 Customer feedback is generated through the corrective action process and through customer surveys that are performed periodically.

#### 5.2.4 ASSOCIATED DOCUMENTS:

- Quality document STAT

### 5.3 Control of Non-Conforming Product and Service

#### 5.3.1 PURPOSE:

This section describes assurance that products or services, which do not conform to specified requirements, are prevented from inadvertent use.

#### 5.3.2 RESPONSIBILITIES AND AUTHORITY:

The operations and area managers/supervisors are ultimately responsible for compliance to this policy and disposition of PPTLI owned product and PPTLI provided service. Quality Assurance is responsible for administration of this policy. Ultimately, the customer/supplier is responsible for disposition of customer/supplier owned parts.

#### 5.3.3 ACTIVITIES:

5.3.3.1 All non-conforming product, whether incoming product, product in- process or at final inspection, or returned from the customer, will be clearly labeled and segregated. Disposition of this product is determined by the product owner.

5.3.3.2 PPTLI product disposition must be signed off by a minimum of one of the following: Area Manager, Marketing, Purchasing or Quality Assurance representative. Customer/supplier owned parts must be dispositioned and signed off by the customer/supplier representative. A Non-Conforming Report form (CNCP form # 1) will be filled out for any product deemed non-conforming by documented or customer supplied requirements.

#### 5.3.4 ASSOCIATED DOCUMENTS:

- Quality document CNCP

### 5.4 Inspection and Testing

#### 5.4.1 PURPOSE:

This section describes the methods used for inspection and testing.

#### 5.4.2 RESPONSIBILITIES AND AUTHORITY:

Quality Assurance is responsible for administration of this policy.

#### 5.4.3 RECEIVING INSPECTION:

5.4.3.1 Receiving inspection of customer or internally purchased parts is performed to ensure all items match those listed on the incoming paperwork. The product is inspected for any obvious outward damage that may have occurred during shipping and parts are counted against required quantities. Product is also inspected for packaging.

5.4.3.2 Results of receiving inspection are recorded on the traveler. The CNCP SOP designates all non-conforming product that shall be documented onto the "Non-Conforming Product Form (CNCP Form #1).

5.4.3.3 All materials, which have a limited shelf life, will be tagged with an expiration date at the time of receipt.

5.4.3.4 The QA department will provide for adequate quality assurance for supplier supplied parts or services. These include supplier surveys and supplier quality control tracking.

#### 5.4.4 IN-PROCESS INSPECTION:

All in-process testing requirements will be clearly indicated in the process documents or on the traveler prior to the release of the lot. Results of the inspection will be indicated on the traveler and signed off or stamped by the appropriate operator prior to moving parts to the next process. Any non-conforming material will be segregated and identified, pending customer disposition.

#### 5.4.5 FINAL INSPECTION:

5.4.5.1 The final inspection process will include documented procedures. All work is verified for assurance of meeting customer requirements. No finished product is released until a final approval C of C and/or stamp has been obtained. The final approval C of C and/or stamp provides traceability to the person(s) authorizing the release.

5.4.5.2 The appropriate customer representative shall be informed of any non-conforming product. Any non-conforming product will be segregated and identified, pending customer disposition.

#### 5.4.6 ASSOCIATED DOCUMENTS:

- Quality document INSP
- Calibration Operating Procedure document CALI

### 5.5 Nonconformity and Corrective Action

#### 5.5.1 PURPOSE

This section describes the necessary actions to control and correct nonconforming outputs (nonconforming products and services) and nonconformities, as well as activities for taking corrective actions to prevent the identified root cause for recurring or occurring elsewhere.

#### 5.5.2 RESPONSIBILITIES AND AUTHORITY

The operations and area managers/supervisors are ultimately responsible for compliance to this policy and for implementing actions and ensuring the effectiveness of corrective actions implemented in their area(s) of responsibility. Quality Assurance is responsible for administration of this policy.

#### 5.5.3 ACTIVITIES

5.5.3.1 Identifying and correcting nonconforming outputs including PPTLI-owned products and services provided to customers, and systemic or process-related problems or undesirable situations such as nonfulfillment of PPTLI process and/or ISO 9001 requirements.

5.5.3.2 Corrective actions are taken in response to information arising from audit results, customer feedback or complaints, supplier/vendor performance data, performance information regarding product and service nonconformity, process monitoring and measurement results, etc. Any actions taken are appropriate to the effects of the nonconformities encountered. The Risk Management Report (MGMT # 3) is updated should the resulting actions affect or instigate any risks. The Opportunities worksheet in the QMS Planning Tool (MGMT #2) is updated should the resulting action affect or instigate any opportunities.

5.5.3.3 Appropriate problem-solving and/or failure analysis methods are used to identify the root cause(s). The root cause investigation attempts to determine if the problem was incident specific or if it is systemic (repeats are distributed over time or happens to different employees performing the same activity).

5.5.3.4 Appropriate corrective actions are taken to eliminate the root causes of existing problems or nonconformities in order to prevent their recurrence or potential occurrence elsewhere.



5.5.3.5 Actions implemented are verified for effectiveness. The objective evidence observed is based on an appropriate time lapse and verification method (observation of work performed, reviewing records, interviewing personnel, etc.).

5.5.3.6 Records of nonconformities and the actions taken, and corrective actions are maintained in accordance with the QREC SOP.

#### 5.5.4 ASSOCIATED DOCUMENTS

- Quality document CNCP
- Quality document CNCP-001 Corrective Action Process
- Quality document INTA
- Quality document MGMT
- Quality document QREC

## 5.6 Management Review

### 5.6.1 PURPOSE

This section describes how Management periodically reviews the QMS as a whole to determine its effectiveness in meeting objectives and applicable requirements, including those of our customers and those of ISO 9001. Management also determines whether the QMS, the quality policy and quality objectives are still suitable and adequate for the company. Management Review Meeting Minutes, documented for each meeting, stand as the records of review. Where actions are required based on information from whatever source, actions are initiated.

### 5.6.2 RESPONSIBILITY AND AUTHORITY

The management representative (the Quality Assurance Manager) is responsible for chairing the management review meeting which will be held annually at a minimum. The President and the operations and area managers/supervisors are responsible for providing input and/or participating in the meeting when requested to do so. Quality Assurance is responsible for administration of this procedure.

### 5.6.3 ACTIVITIES

5.6.3.1 Quality Assurance schedules the management review meetings and ensures that data is provided and prepared as appropriate to address during the review meeting.

Items covered at the management review will be at a minimum:

- Actions decided during previous management reviews,
- Changes in external and internal issues that are relevant to the QMS
- Information on the performance and effectiveness of the QMS including trends in:
  - Customer satisfaction and feedback from customers and other relevant interested parties
  - The extent to which quality objectives have been met
  - Process performance and nonconformity of products and services
  - Monitoring and measurement results
  - Audit results
  - the performance of external providers (suppliers and vendors)
- The adequacy of resources
- Review of quality policy and objectives
- The effectiveness of actions taken to address risks and opportunities
- Opportunities for improvement

5.6.3.2 Quality Assurance documents the outputs from the management reviews include decisions and actions related to:

- Opportunities for improvement
- Any need for changes to the QMS
- Resource needs.

5.6.3.3 Quality Assurance ensures that actions resulting from the reviews are completed.

5.6.3.4 Records of the meeting minutes are retained in accordance with the QREC SOP.

#### 5.6.4 ASSOCIATED DOCUMENTS

- Quality document MGMT
- Quality document QREC

### 5.7 Continual Improvement

#### 5.7.1 PURPOSE

This section describes how PPTLI considers the results of analysis and evaluation, and the outputs from management reviews to determine if there are needs or opportunities that should be addressed to improve the suitability, adequacy and effectiveness of the quality management system.

#### 5.7.2 RESPONSIBILITIES AND AUTHORITY

The operations and area managers/supervisors are ultimately responsible for compliance to this policy and for implementing improvements implemented in their area(s) of responsibility. Quality Assurance is responsible for administration of this policy.

#### 5.7.3 ACTIVITIES

5.7.3.1 Actions taken to plan and implement improvements stemming from any source that provide an increased ability to fulfill requirements and enhance customer satisfaction.

5.7.3.1 Effectiveness of the improvements are demonstrated by measurable results or quantifiable benefits (or estimates thereof).

#### 5.7.4 ASSOCIATED DOCUMENTS

- Quality document MGMT
- Quality document INTA
- Quality document CNCP