

# **LPS / PT LABORATORIES**

## **QUALITY MANUAL**

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Reviewed By: Laura James

Title: Quality Assurance  
Supervisor

Signature \_\_\_\_\_

Date: 6/4/04

Approved By: Ed Williams

Title: Technical Manager

Signature \_\_\_\_\_

Date: 6/4/04

Signatures on file in **Human Resources Manager's** office

<b>SUBJECT:</b> 0.0    INTRODUCTION
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LPS / PT is a manufacturer of high performance maintenance and repair chemical products for various industries. LPS / PT has established and will maintain a continuous quality improvement system that enables us to consistently satisfy our internal requirements with consideration to our customers' expectations.

Quality improvement is a team effort and a responsibility shared by employees at all levels of the organization. Quality improvement is key, not only to our success, but to our survival in a competitive marketplace.

The ISO 9001 (ver. 1994) Quality Standard, which we have adopted, documents our commitment to quality improvement. The documents which follow comprise our Quality Manual which details our quality improvement system as stipulated in the above mentioned standard.

<b>SUBJECT:</b> 1.0    SCOPE & FIELD OF APPLICATION
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**The mixing, blending, and packaging of chemical products for maintenance, repair and operation in an industrial, aerospace, power and telecommunications environment.**

<b>SUBJECT:</b> 2.0    REFERENCES
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#### REFERENCES

The Quality Assurance Procedures  
ISO 9001 Standard (ver. 1994) Elements 4.1-4.3 and 4.5-4.20

<b>SUBJECT:</b> 3.0    DEFINITIONS
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Contract - Customer Order

Corrective Action - Activity taken to resolve actual incidences of product and system nonconformance.

Customer Order - Any verbal or written request from a customer for Product, including price, method of shipment and payment terms.

Customer Supplied Product - Any raw material supplied by the customer to LPS / PT for incorporation into manufactured finished goods.

Document - Any written information used in the daily activities at LPS / PT which are relied on as basis, proof, and support of the Quality System. Information may be in any media form, from an internal/external source and include but not be limited to: process requirements, specifications, drawings, technical data and forms.

Finished Goods/Product - Product which has completed the manufacturing process and is ready for sale.

First Run Production Article - For aerosol products, this is the first two aerosol samples per production run. For liquid products, this is the 8 oz. liquid sample called the "pre-run filling sample".

In - Process Testing - Those tests performed upon materials during stages of manufacturing to ensure adherence to specification.

Inspection - Performing activities such as measuring, examining, testing or gauging one or more characteristics of a product and comparing those characteristics to specified requirements to determine conformity.

Key Characteristic - The feature of a material or part whose variation has a significant influence on product fit, performance, service life or manufacturability.

Nonconforming Product - Any raw material, material in the manufacturing process, or finished product which does not meet quality specifications.

Nonconformity - Any instance where Product or activities do not comply to quality specification or quality policies set forth in the Quality System.

Preventive Action - Activity taken to resolve potential incidences of product and/or system nonconformance.

Procedure - Outline of activities critical to the maintenance of quality describing the whom, what, when, where and how an activity is carried out when accompanied by a detailed work instruction

Product - Any good or packaged good manufactured by LPS / PT or one of it's vendors which is intended for offering to the customer.

Production Process - The standard operating methods and manufacturing cycle used in producing a finished good from beginning to end.

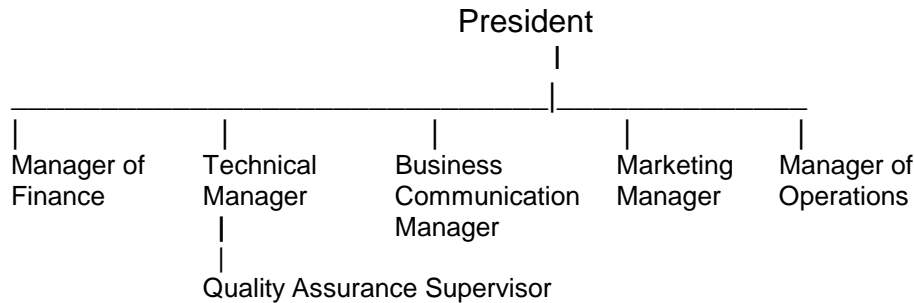
Purchased Product - Any material purchased by LPS / PT for use in manufacturing or resale to the customer.



4.1.2 ORGANIZATION

4.1.2.1 RESPONSIBILITY AND AUTHORITY

Management Responsibility Organization Chart



All executive management personnel have responsibility and authority for managing, performing and verification of work that affects quality. All LPS / PT employees have responsibility for quality and for initiating corrective or preventive action within the scope of their job function. This includes the suggestion, implementation, and verification of corrective actions, as appropriate. LPS / PT employees have the authority to stop a process in their area of responsibility if quality standards are not being met.

4.1.2.2 RESOURCES

LPS / PT Laboratories shall verify that product meets specified requirements and that manufacturing, packaging, shipping, etc. conforms to documented procedures. Adequate resources such as space, equipment, facilities and personnel shall be provided. Testing, inspection and audit functions shall be performed by qualified personnel. Internal audits of the Quality Management System shall be conducted by qualified personnel independent of those having responsibility for the work being performed **as outlined in QA 6.0.**

4.1.2.3 MANAGEMENT REPRESENTATIVE

The Quality Assurance Supervisor is responsible for implementation and maintenance of the Quality Management System. Responsibilities include organizing internal audits, interfacing with external (customer or FDA) auditors and reporting to management on the performance of the system.

**4.1.3 MANAGEMENT REVIEW**

**4.1.3.1 GENERAL**

Management reviews are conducted in accordance with QA 7.0 to ensure continuing suitability, adequacy, and effectiveness of the QMS. The reviews assess opportunities for improvement and the need for changes to the QMS, including the quality policy and any objectives. Minutes of management reviews are maintained.

**4.1.3.2 REVIEW INPUT**

Management reviews include information on results of audits, customer feedback, process performance, product conformity, status of preventive and corrective actions, follow-up actions from previous management reviews, changes that could affect the QMS, and recommendations for improvement.

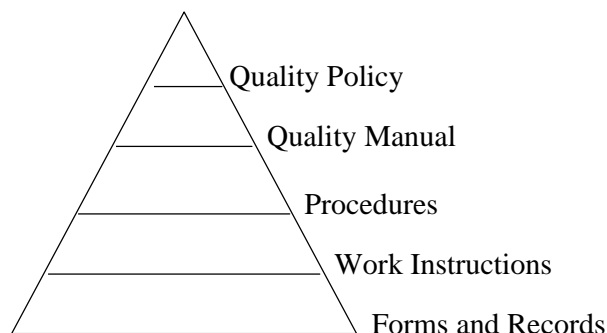
**4.1.3.3 REVIEW OUTPUT**

The output from management reviews includes any decisions and actions related to improvement of the effectiveness of the QMS and its processes, improvement of the product related to customer requirements, and resource needs.

<b>SUBJECT:</b> 4.2    QUALITY SYSTEM
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**4.2.1 GENERAL**

LPS / PT has established a Quality System as a means of ensuring that product conforms to specified requirements. The Quality Manual covers the requirements of ANSI/ASQC ISO 9001-1994 and outlines the structure of the documentation used in the Quality System.



**4.2.2 QUALITY SYSTEM PROCEDURES**

LPS / PT shall prepare documented procedures that are consistent with the requirements of this Quality Manual and the stated policy. The LPS / PT Quality Manual and associated procedures are readily available upon request, to compliance personnel, customers, and outside regulatory agencies.

**4.2.3 QUALITY PLANNING**

LPS / PT defines and documents how the requirements for quality will be met. Quality plans are consistent with the other requirements of the Quality System, and documented in a format to meet individual departmental methods of operation. LPS / PT gives consideration to the following activities in meeting the specified requirements for products:

- a) Prepares quality plans
- b) Identifies and/or purchases controls, processes, equipment, resources, and skills that may be needed to achieve the required quality. LPS / PT does not utilize any design tooling in the manufacturing process at this time and as such does not identify this control in the quality plan.
- c) Ensures the compatibility of the production process, inspection, and test procedures and the applicable documentation.
- d) Updates, as necessary, quality control, inspection and testing techniques.
- e) Identifies any measurement requirement involving capability that exceeds known state of the art in sufficient time for capability to be developed.
- f) Identifies verification at appropriate stages during the manufacturing process. This also includes the identification of in-process verification points as necessary.
- g) Clarifies the standards of acceptability for all product features and requirements.
- h) Identifies and prepares quality records.
- i) The identification and selection of subcontractors capable of meeting quality requirements and the appropriate flowdown of quality requirements.
- j) The establishment of appropriate process controls and the development of control plans of key characteristics if required by customer.

<b>SUBJECT:</b> 4.3    CONTRACT REVIEW
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**4.3.1 GENERAL**

Before the acceptance of a customer order, all customer orders are reviewed and **any discrepancies are resolved as outlined in CS 1.0.**

4.3.2 REVIEW

All questions will be resolved regarding written or verbal customer orders so that order criteria may be met. Contract review will ensure LPS / PT's ability to meet the contract requirements and verify contract accuracy.

4.3.3 AMENDMENT TO A CONTRACT

Any amendment to a contract/customer order will be verbally confirmed with the customer. If necessary, others will be notified. **Order changes are discussed in CS 2.0.**

4.3.4 RECORDS

Customer invoices, computer order input, and Bills of Lading serve as customer order confirmation.

<b>SUBJECT:</b> 4.5    DOCUMENT & DATA CONTROL
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4.5.1 GENERAL

Control shall be exercised over the issue, distribution and change of all quality system documents including documents of an external origin **as outlined in QA 5.0**. These documents will be reviewed for adequacy by authorized personnel prior to issue.

4.5.2 DOCUMENT & DATA APPROVAL & ISSUE

Each department manager/designee will maintain their department's master documents and be responsible for document control which includes approvals, document identification, revision/issue dates, retention and distribution to appropriate people and sites. Any obsolete documents retained for legal and/or knowledge preservation purposes will be suitably identified.

4.5.3 DOCUMENT & DATA CHANGES

Document changes will be identified by revision number, revision date, and if practical, boldfaced type (i.e. Quality Manual, Procedures, Work Instructions). Previous changes in bold will be converted to normal type after the document has been in circulation for six months, or if another revision is created. All document changes will be reviewed and approved by authorized personnel as designated by the department manager. Access to pertinent background information upon which to base their review and approval will be afforded to authorized personnel. Each department will be responsible for ensuring distribution and control of the most recent issue of each document and destruction of obsolete documents. Documents shall be promptly reissued upon any changes or modifications.

A master list of all quality system documents will be maintained by the Quality Assurance Supervisor. When applicable, any records regarding change of procedures, drawings, standards, specifications, and quality plans shall be included in the controlled document master list.

<b>SUBJECT:</b> 4.6 PURCHASING
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#### 4.6.1 GENERAL

Purchasing shall maintain documented procedures to ensure that purchased products conform to specified requirements.

#### 4.6.2 EVALUATION OF VENDORS

All vendors to LPS / PT are selected and reviewed upon their ability to supply quality products per contract requirements, including the quality system **as described in PU 3.0**. This selection and review includes but is not limited to the vendor's ability to meet requirements for quality, service and price. The type and extent of control will be based upon performance documentation and reviews with consideration given to the impact of the vendor supplied product or service on the quality of the final product. An approved vendor list, including the names of approved sub-contractors will be maintained in the purchasing department. At this time, LPS / PT does not use customer approved special process sources.

#### 4.6.3 PURCHASING DATA

All purchasing data will contain a clear description of the product ordered including type, class grade or other precise identification. When necessary, purchasing data will include process requirements, inspection instructions, and other relevant technical data or testing requirements such as certificates of conformance. All purchasing documents will be reviewed and approved for conformance to requirements, and adequacy of specifications by the purchasing department.

#### 4.6.4.1 LPS / PT VERIFICATION AT VENDORS PREMISES

Where LPS / PT proposes to verify purchased product at the vendor's premises, LPS / PT shall specify verification arrangements and the method of product release in the purchasing documents **as described in PU 12.0**. This control may include vendor certifications, incoming receiving, and the delegation of verification to the subcontractor.

**4.6.4.2 LPS / PT CUSTOMER VERIFICATION OF SUBCONTRACTOR PRODUCTS**

The customer, where specified by contract, is afforded the opportunity to verify that purchased product conforms to specified requirements. Verification may be performed at the source, or upon receipt of product at LPS / PT.

Product verification by the customer shall not be used as evidence of effective control of quality by LPS / PT. This shall not absolve LPS / PT of its responsibility to provide acceptable products nor shall it preclude subsequent rejection by the customer. LPS / PT shall not use such verification as evidence of effective quality control.

<b>SUBJECT:</b> 4.7 CONTROL OF CUSTOMER SUPPLIED PRODUCT
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**As a part of its private label business, PT stores and uses labels imprinted with a customer-owned image. This image is electronically transmitted from the customer to LPS' marketing department and is incorporated into our label generation process. The same care is taken with a customer-supplied image as is taken with any LPS or PT image. If the label image is found to be unsuitable for use, or is lost or damaged, this information is communicated to the customer and records are maintained in the marketing department (see MK 3.0).**

**Verification by LPS/PT does not absolve the customer of the responsibility to provide acceptable product.**

<b>SUBJECT:</b> 4.8    PRODUCT IDENTIFICATION AND TRACEABILITY
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**Procedure QC 4.0 describes how product is identified from receipt through manufacturing and delivery.**

**Traceability, although not required in most cases, is maintained by uniquely identifying individual batches and product runs. The traceability system is documented in QC 7.0 and QC 8.0. Records are retained in accordance with the requirements of section 4.16.**

<b>SUBJECT:</b> 4.9    PROCESS CONTROL
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LPS / PT shall identify and plan production processes which directly affect the ability of our products to meet their specified requirements. These processes shall be carried out under controlled conditions which include but will not be limited to the following:

- a) documented work instructions defining the manner of production;
- b) suitable production, installation and servicing equipment and a suitable

- working environment;
- c) compliance with applicable reference standards, documented procedures and in accordance with the quality plans;
  - d) monitoring and control of suitable process and product characteristics (including key characteristics, when required by contract), during production:
  - e) the approval of processes and equipment, as appropriate;
  - f) criteria for workmanship which shall be stipulated by the appropriate Batch Control Sheet and associated Procedures, or by means of representative samples.
  - g) suitable maintenance of equipment to ensure continuous process capability.

**Neither LPS nor PT use processes where the resulting output cannot be verified by subsequent monitoring or measurement. In the event that such processes are identified, they will be** monitored to ensure that specified requirements are met. The processes shall be carried out by qualified operators. In addition, records shall be maintained for processes, equipment, and personnel, as appropriate (see 4.16). The requirements for any qualification of process operations, including associated equipment and personnel shall be specified. (see 4.18).

<b>SUBJECT:</b> 4.10 INSPECTION AND TESTING
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#### 4.10.1 GENERAL

LPS / PT will establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for product are met. The required inspection and testing and the records to be established, shall be detailed in the quality plan or documented procedures. LPS / PT will utilize subcontractor requirements outlined in the purchasing section of this manual when subcontractors are required to perform inspection activities.

#### 4.10.2 RECEIVING INSPECTION AND TESTING

LPS / PT shall ensure that incoming materials and products are not used or processed until they have been inspected or otherwise verified as conforming to specified requirements. Inspection and verification shall proceed as detailed in the appropriate procedures (**see QC 6.0, QC 24.0 and QC 25.0**). Consideration shall be given to the amount of control exercised at the vendor's premises and certificates of conformance supplied. **If incoming product is released for urgent production purposes prior to verification, it is positively identified and recorded in order to permit immediate recall and replacement in the event of nonconformity to specified requirements.** LPS / PT will validate certificates of conformance on designated frequencies as a means of product acceptance.

4.10.3 IN-PROCESS INSPECTION AND TESTING

**Batches of LPS and PT products are monitored and inspected as described in QC 2.0 and the batch control sheet. As product is being filled, it is monitored and measurements are taken as described in QC 7.0 and QC 8.0.**

Quality control personnel authorize the release of product and maintain records of product conformity with acceptance criteria.

Product that does not meet specifications may be released in accordance with QC 11.0. If required by contract, LPS/PT will not release product until it meets specifications unless the customer authorizes the release. **LPS / PT shall not release any finished product until all testing is complete.**

4.10.4 FINAL INSPECTION AND TESTING

**Once a product is packaged, it is evaluated according to the finished goods evaluation procedure, QC 22.0.** Final inspection and testing will complete the evidence of conformance of finished products to their specified requirements. No product shall be released until appropriate conformance verification procedures have been satisfactorily completed and associated data and documentation are available and authorized.

4.10.5 INSPECTION AND TEST RECORDS

LPS / PT shall establish and maintain records which give evidence that products have been inspected and/or tested and shall show clearly whether the product has passed/failed inspection according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply. (see 4.13)

Procedures and/or Work Instructions shall identify the inspection authority responsible for the release of product. LPS / PT will maintain procedures, as appropriate, for the inspection, verification, and documentation of first run production articles

<b>SUBJECT:</b> 4.11 CONTROL OF INSPECTION, MEASURING & TEST EQUIPMENT
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**Several pieces of equipment including scales, crimp gauges, pH meters, density cups, and viscometers are used to measure product characteristics and fill weights. Each piece is identified on the calibration log and assigned an appropriate calibration frequency. A qualified calibration laboratory performs the calibrations using NIST-traceable standards and identifies the calibration status by attaching a calibration sticker to each piece of equipment. The Quality Control department maintains records of calibration. QC 13.0 describes how the organization controls, calibrates and maintains inspection, measuring and test**

equipment used to demonstrate the conformance of product to specified requirements. In addition this procedure describes actions taken if equipment is found to be out of calibration.

Where computer software is used as a suitable form of inspection, it is checked and rechecked, as appropriate, to ensure that it is capable of verifying acceptability of product.

Where the availability of technical data pertaining to the measurement equipment is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the measuring equipment is functionally adequate.

LPS / PT, through the **Technical Manager** and/or **Manager** of Operations, or designee shall:

- a) Determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring, and test equipment that is capable of the necessary accuracy and precision;
- b) Identify all inspection, measuring and test equipment that can affect product quality and have them calibrated and adjusted at prescribed intervals against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exist, the basis used for calibration shall be documented;
- c) Define the criteria for calibration of inspection, measuring and test equipment. LPS / PT shall maintain a master list of all equipment requiring calibration, including details of equipment type, unique identification, location, frequency of checks, acceptance criteria and action to be taken when results are unsatisfactory. Procedures are also in place for the recall of inspection equipment as appropriate.
- d) Equipment will be tagged with last inspection date and Pass/Fail. Date for next inspection and ID of person conducting inspection will be recorded for all equipment;
- e) Records will be maintained in the equipment status file;
- f) Calibration equipment capability is measured against defined standards. When out of calibration, previous test results will be reviewed, assessed and documented. Procedures for calibrating and actions to take if results are unsatisfactory are in the equipment status file;
- g) Ensure that the environmental conditions are suitable for calibration, inspections, measurements, and tests being carried out;
- h) Confirm that inspection, measuring and test equipment is handled, preserved and stored in a manner such that accuracy and fitness for use are maintained;
- i) Require that the inspection measuring and test facilities including both test hardware and software are safeguarded from adjustments which would invalidate the calibration setting.

<b>SUBJECT:</b> 4.12 INSPECTION & TEST STATUS
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Inspection and test status shall be identified by the QC Chemist using an authorized mark or physical location which indicates conformance.

Nonconforming product is segregated so only conforming product is used in production and/or identified as approved finished goods. Controlled documents reference acceptance media used for accepted or rejected materials.

<b>SUBJECT:</b> 4.13 CONTROL OF NONCONFORMING PRODUCT
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#### 4.13.1 GENERAL

**LPS and PT ensure that product that does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in QC 11.0 and PR 56.0.**

#### 4.13.2 REVIEW AND DISPOSITION OF NONCONFORMING PRODUCT

**Quality control maintains records documenting the nature of nonconformities and any subsequent actions taken, including concessions obtained.**

**Whenever nonconforming product is corrected, it is re-inspected to ensure conformity to requirements. Should the customer experience problems after receipt, LPS/PT will replace the product or issue a credit if it is returned within the warranty period.**

<b>SUBJECT:</b> 4.14 CORRECTIVE & PREVENTIVE ACTION
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#### 4.14.1 GENERAL

**Procedures QA 2.0 and QA 2.1 describe the corrective/preventive action process.** Corrective and preventive action will be applied to a degree appropriate to the magnitude to potential problems and risks encountered. Changes to documented procedures resulting from corrective and preventive actions are recorded and implemented. **Corrective/preventive actions are documented in the quality activity log.**

#### 4.14.2 CORRECTIVE ACTION

Corrective action will be initiated where product, process and system nonconformance are found as a result of:

- a) Internal and external Quality Audits
- b) Customer complaints and reports of product non-conformities
- c) Manufacturing Process Audits
- d) Continuous and informal observations by employees
- e) Market feedback

Procedures for corrective actions include:

- a) The effective handling of customer complaints and reports of product nonconformities.
- b) An investigation and recording of the cause of nonconformities
- c) Identification of the corrective action needed to eliminate nonconformities
- d) Implementation of corrective action and controls to ensure that it is effective.

#### 4.14.3 PREVENTIVE ACTION

Preventive action will be taken to eliminate potential causes of nonconformities. Procedures for preventive action include:

- a) Information sources to detect and analyze and eliminate potential causes of nonconformities
- b) Determination of the steps needed to deal with any problems requiring preventive action
- c) Implementation of preventive or corrective actions and controls to ensure that it is effective
- d) Confirmation that preventive action taken is submitted for management review.

<b>SUBJECT:</b> 4.15 HANDLING, STORAGE, PACKAGING, PRESERVATION & DELIVERY
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#### 4.15.1 GENERAL

LPS / PT materials and products are handled, stored, packaged, preserved and delivered in accordance with the guidelines referenced below.

#### 4.15.2 HANDLING

LPS / PT provides suitable methods for handling that prevent damage and deterioration.

#### 4.15.3 STORAGE

LPS / PT stores materials to prevent damage or deterioration of product pending use or delivery. The condition of the product in stock is assessed at appropriate intervals.

#### 4.15.4 PACKAGING

Packaging and labeling are performed in accordance with agreed upon requirements. Our goal is to make every effort to ensure that the delivered product is properly identified and undamaged to the customer.

#### 4.15.5 PRESERVATION

LPS / PT stores materials so that they do not deteriorate or change the quality of the product beyond normal aging. Preservation and segregation processes are performed in accordance with agreed upon requirements.

#### 4.15.6 DELIVERY

Delivery arrangements are made to ensure the protection of product quality after final approval. Where contractually specified, this protection is maintained during delivery to destination.

<b>SUBJECT:</b> 4.16 CONTROL OF QUALITY RECORDS
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Procedures exist for identification, collection, indexing, accessing, filing, storage, maintenance, and disposition of quality records.

Quality records are maintained to demonstrate achievement of the required quality and the effective operation of the quality system. Pertinent vendor quality records shall be an element of these data.

All quality records shall be legible, suitably stored to prevent damage, deterioration or loss, and shall be easily retrievable. Retention times of quality records shall be appropriate to each department's requirements, and are stated in the controlled document master list. Product related records will be maintained for the active life of the product.

Upon an approved request, quality records are made available to our customers or regulatory agencies. Accessibility of quality records will be to department managers and designated people.

<b>SUBJECT:</b> 4.17 INTERNAL QUALITY AUDITS
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LPS and PT periodically conduct internal audits to determine whether the QMS conforms to the organizations' requirements, this quality manual and related procedures, and the requirements of ISO 9001. The audits are also used to determine if the QMS is effectively implemented and maintained. In order to maintain impartiality and objectivity, auditors never audit their own work.

The internal audit procedure, QA 6.0, contains the responsibilities and requirements for scheduling, planning, and conducting the audits, reporting the results, and maintaining records. The procedure also describes how follow-up, verification, and related reporting are accomplished. Department managers are responsible for taking appropriate and timely corrective actions in response to audit nonconformities.

<b>SUBJECT:</b> 4.18 TRAINING
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Employees are trained to the skill level necessary to perform their jobs to the quality standards required. Personnel are qualified to perform specific tasks on the basis of appropriate education, training, and/or experience. The Personnel Administrator maintains copies of training records/certificates in each employee file. (see 4.16).

Competence requirements are outlined in each employee's job description. In general, all employees must be able to read and understand LPS/PT's product and process documents, as evidenced through training and evaluations performed by their supervisor and documented in their personnel files. All managers must be able to communicate effectively both verbally and in writing, as evidenced by high school diplomas or equivalent documentation.

Personnel may be trained internally as well as externally when training needs are identified. In most cases, the employee's supervisor will assess the effectiveness of the training. However, if specialized skills are learned and a supervisor does not possess the knowledge to assess effectiveness, the employee's self-assessment is deemed appropriate. In addition, self-assessments are considered appropriate for members of management. In any case, the assessment will be documented and retained in the employee's personnel file. Personnel records hold the appropriate records of education, training, skills, and experience.

<b>SUBJECT:</b> 4.19 SERVICING
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Servicing is not a specified requirement of the LPS / PT Quality System based upon the standard (ANSI/ASQC Q9001-1994) and thus, does not apply.

<b>SUBJECT:</b> 4.20 STATISTICAL TECHNIQUES
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#### 4.20.1 IDENTIFICATION OF NEED

LPS / PT shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics.

#### 4.20.2 PROCEDURES

Procedures exist to implement and control the application of the statistical techniques identified in 4.20.1.

#### 4.20.3 SAMPLING INSPECTION

Periodic sampling for in-process inspection shall be appropriate for use.  
END