**QUALITY MANAGEMENT SYSTEM**

Larson Davis a Division of PCB Piezotronics, Inc.

1681 WEST 820 NORTH

PROVO, UTAH 84601

“Total Customer Satisfaction”

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# 1.0 INTRODUCTION

## 1.1 Purpose

The Quality Management System (QMS) is the framework for the administration of the quality system at Larson Davis a Division of PCB Piezotronics, Inc. Several national and international standards are used as references in developing the quality system including but not limited to:

* ISO 9001-2015 Quality Management System—Requirements
* ISO 17025—General requirements for the competence of testing and calibration laboratories
* ANSI Z540-1 Calibration Laboratories and Measuring and Test Equipment—General requirements
* ISO/IEC 80079-34 Explosive Atmospheres—Part 34: Application of quality systems for equipment manufacture

The use of multiple standards and internal policies and procedures determined by the company in building the framework allows Larson Davis to enhance our customers’ “Total Customer Satisfaction”. The implementation of the quality management system extends to all departments, processes and employees.

Larson Davis a Division of PCB Piezotronics, Inc. has adopted the ISO 9001 standard for our quality management system in the effort to improve our overall performance and provide a basis for the sustainable development of initiatives. This process approach incorporates planning, doing, reviewing and acting cycles along with risk-based thinking, that enables our organization to plan our processes; and their interactions, to ensure our processes are adequately resourced and managed, and that opportunities for improvement are determined and acted upon. Risk-based thinking enables our organization to determine factors that could cause our processes and quality management system to deviate from planned results, and to implement preventive controls to minimize negative effects and make maximum use of opportunities as they arise. Understanding and managing the interrelated processes of our quality management system contributes to our organizations effectiveness and efficiency in achieving the intended results for our products and services.

The review and approval of the Quality Management System and risks associated with meeting the company objectives is the responsibility of the Director of LD Operations (DOO)/General Manager (GM) of Larson Davis.

The company management structure is:

The LD Management team interfaces with the PCB Piezotronics Management team and has control of day-to-day activities at Larson Davis. The Management team at LD includes the following positions:

Director of LD Operations/General Manager

Engineering Manager

Sales Division Manager

Product Manager

Production Manager

Logistics Manager

The company Human Resource Department maintains the organizational charts that detail the relationships between corporate management, LD Division Management and other managers and job functions. Employees access that information online or by contacting the DOO/GM.

## 1.2 Company Profile

**Larson Davis**

Brian Larson and Larry Davis founded Larson Davis in 1982. The business evolved from a small Company to an engineering and manufacturing operation recognized as a worldwide leader in acoustic noise measurement and monitoring. The technical efforts of the Company produced such world leading instruments as the 800B, 700 and 710. Microphones and analyzers were added to the product line as the Company continued to grow and work on several military projects that resulted in the addition of the 3100 and 3200 analyzers. Further growth resulted in the Company moving to Provo, Utah in 1988 where the Company purchased two new software companies and became a public Company with the merger of a Nevada NASDAQ Company and Larson Davis.

Environmental monitoring instruments were added to the product line with the release of the 870 and 2100K. LD also released a portable two-channel analyzer, the 2900, which became a world leader in the industry. Growth through the purchase of other instrumentation companies and the closure of the software companies continued through the 1990s.

In April 1999 assets of Larson Davis were sold to PCB Piezotronics of Buffalo, New York. On December 31st, 2006, Larson Davis, Inc. merged with PCB Piezotronics, Inc. and LD became a division of that organization.

Our philosophy of doing everything possible to serve customer needs is our focus. We have built a loyal customer base by providing quality products at reasonable prices, on a quick-delivery basis. Our vision of ***“Total Customer Satisfaction”*** supports our philosophy to provide superior customer service.

 **PCB Piezotronics, Inc**

Our name "PCB" is an acronym for "PicoCoulomB" which is technical terminology defining an electrical charge of the type generated by the piezoelectric sensors we manufacture. "Piezotronics" combines the science of Piezoelectricity and electronics. At PCB we manufacture "sensors" which are basically small electromechanical instruments for the measurement of dynamic pressure, force, shock, vibration and sound. Automotive manufacturers use PCB sensors to measure the sound and vibration level of new cars they are designing and testing to improve quality and customer appeal.

PCB Piezotronics Inc. was founded in 1967 as a manufacturer of piezoelectric quartz sensors, accelerometers, and associated electronics for the measurement of dynamic pressure, force, and vibration. The unique expertise of the company was the incorporation of microelectronic signal conditioning circuitry within these sensors to make them easier to use and more environmentally compatible. These ICP® sensors gained wide popularity and became the foundation for the company's success.

Subsequent growth and steady investment in facilities, machinery, and equipment permitted a constant broadening of the product offering. Measurement capabilities expanded with the addition of piezoceramic, tourmaline, capacitive, piezoresistive, and strain gage sensing technologies. Ensuing products include industrial accelerometers, DC accelerometers, load cells, torque sensors, microphones, pressure transmitters, and calibration equipment.

PCB’s World Headquarters and Technology Center is located on a six-acre campus outside of Buffalo, NY. The campus includes PCB’s 100,000 sq. ft. (9290 sq. m.) main building and a separate 50,000 sq. ft. (4645 sq. m.) building housing the Precision Machining Center. Other facilities include Halifax, NC producing Piezoelectric, ICP®, piezoresistive, acoustic, force, shock & vibration sensors; PCB Load & Torque located in Farmington Hills, MI producing precision load cells, wheel force transducers, torque transducers, telemetry systems, and fastener torque-tension test systems; Larson Davis located in Provo, UT, producing precision microphones, sound level meters, noise dosimeters, audiometric calibration systems; Accumetrics located in Latham, NY producing digital rotor telemetry (the wireless acquisition of measurement signals from the rotors of rotating machines); and The Modal Shop located in Cincinnati, OH, offering a complete line of automated calibration systems and recalibration services to support dynamic vibration, shock, pressure, and force sensors.

 **MTS Corporation**

On July 5, 2016 MTS, a test and sensor company purchased all of the stock of PCB Group. MTS is a publically traded company with two divisions that operates very similar to PCB. The sensor division of MTS was merged with PCB into one operating unit.

Although the company has grown steadily over the years and changed in many ways, our philosophy of doing everything possible to serve customer needs remains unchanged. We have built a loyal customer base by providing quality products at reasonable prices, on a quick-delivery basis. Our vision of *"Total Customer Satisfaction"* supports our philosophy to provide superior customer service.

The success of PCB is in our people. It is our management philosophy to hire good people and support them in doing whatever job they do best. All of us at PCB feel very strong about ethics and honesty. At PCB we operate on a first name basis.

Management is committed to quality, risk assessment and providing a friendly, supportive and challenging work environment. The company's locations, pleasant working conditions, progressive benefits package and opportunities for advancement create a spirit of enthusiasm that provides PCB with a definite "competitive edge".

## 1.3 Business Classification and Statements of Compliance

PCB Piezotronics, Inc. complies and/or can be identified according to the following characteristics:

1. Is a large business, which currently employs approximately 770 people, and when combined with other PCB Group affiliated companies, employs approximately 900 people.
2. Is an equal opportunity employer that posts EEO notices in our non-segregated facilities and annually files EEO-1 reports.
3. Has developed an affirmative action program.
4. Complies with all requirements associated with Clean Air and Water Certification.
5. Has **never** been on the EPA List of Violating Facilities.
6. Meets all local, State and Federal environmental laws and regulations per facility locations.
7. Is entirely US owned and operated.
8. Operates a drug-free workplace.
9. Is not located in a Labor Surplus Area.
10. Has not used federally appropriated funds for the purpose of influencing any government employee.
11. Has not provided, attempted to provide, offered, solicited or accepted any kickback.
12. Is not currently and has never been debarred, suspended, proposed for debarment or declared ineligible for award of public contracts or grants by any federal agency.
13. Has not been convicted of or had a judgment rendered against it or been indicted for commission of fraud or criminal offense connected with a public contract or violation of federal or state antitrust statutes or similar criminal offenses.
14. Has never defaulted on any public contract, grant or loan.
15. Prices its products independently without agreement with any other offer or competitor of a public solicitation.
16. Does not use in any process or manufacture any products, which contain ozone-depleting substances as identified by state requirements per facility locations.
17. Is an open shop with no union affiliations.
18. Complies with all applicable OSHA regulations per facility locations.

## 1.4 Internal Structure

PCB has implemented integrated facilities, which includes most steps from initial sale to product shipment. This continuous reinvestment into facilities and equipment provides a high degree of self-sufficiency and offers flexible manufacturing, fast prototyping and customization services to meet developmental needs. Following is a detailed description of PCB’s equipment and facilities.

Sales and Marketing: The sales and marketing staff has over 90 full time employees dedicated to sales and customer service: approximately 60 in Domestic Sales, 25 in International Sales, 10 for Marketing and additional support personnel. Their efforts are supported by an extensive network of direct sales offices, which can be found in the USA as well as in Canada, Germany, France, Italy, United Kingdom, Japan, China and Sweden. This combined sales force serves as an efficient vehicle for supporting existing products as well as for bringing new technology to the market. Currently, PCB Piezotronics realizes approximately 55% of its annual sales volume in the USA.

Engineering: The engineering staff consists of over 90 full-time engineers and 15 support personnel. Approximately 20 of the engineers and 5 support personnel are dedicated full-time to R&D of new technologies, while the remaining personnel work on designing custom application solutions or manufacturing continuous improvement. All personnel rely heavily on tools such as Design for Six Sigma (DFSS), Design or Process Failure Mode and Effects Analysis (D/P-FMEA), Design of Experiments (DOE), Finite Element Analysis (FEA) and Circuit Simulations, to rapidly evaluate and diagnose complex electrical, mechanical and electromechanical designs and AGILE software development methodology. In addition, CAD/CAM tools allow accurate documentation and quick prototyping. Automated test equipment, environmental chambers, analyzers, digital oscilloscopes, shakers, shock tubes and other similar test equipment allow engineers to fully evaluate and test devices under a range of operating conditions.

Manufacturing: Utilizing approximately 2/3 of individual facilities and typically operating at 50% capacity, exceptional capability exists in transducer and signal conditioner manufacturing. Three production shifts, totaling approximately 400 personnel, utilize highly sophisticated, computer controlled, automated machining equipment, including CNC mills, dual-spindle lathes, swiss-style screw machines, punch presses, wire EDM’s, and lapping wheels. In addition to the primary production operations, ten tool room lathes are dedicated to small quantity runs for prototypes and customer specials. Approximately 150,000 precision-machined parts are produced each month by our Machining Department. Automatic wirebonders, pick-and-place machines and laminar flow clean benches are used for fabricating the miniaturized electronic circuits, which are incorporated into most of the sensors. Other manufacturing capabilities include: laser welding, laser marking, grinding, sandblasting, wave soldering, hermetic connector and crystal manufacturing. Final products are tested under a variety of conditions using automated calibration workstations accredited to ISO17025, which utilize NIST and/or European PTB traceable standards.

Administration / Support: Approximately 50 personnel are utilized for various administrative and support functions, which include human resources, accounting, information technology, and legal.

Each employee’s job responsibilities and work instructions define the methods by which they support the customer’s needs, their direct supervisor and/or Senior Leadership Team member supports each employee.

## 1.5 Organization Structure:

Key components of the PCB organization are defined as follows:

 **President**

 **Senior Leadership Team**: Directors, Vice-Presidents, Managers and General Counsel directly reporting to President.

 **Manufacturing Centers**: Pressure, Force, Vibration, MEMS Products, Microphones, Acoustic products, Electronic products and custom products.

 **Functional Support Groups**: Marketing, Quality Assurance, Human Resources, Finance, and Legal.

## 1.6 Quality Management System Certification Information:

PCB Piezotronics Inc. Headquarters facility located at 3425 Walden Avenue, Depew, New York**:**

The quality management system is certified to the International Quality Standards AS9100 and ISO9001 with scope of certification defined as: *The design, manufacture, repair and recertification of sensors and signal conditioning electronics used for measurement of pressure, force, shock, or vibratory motion for commercial, military and aerospace applications. The manufacture of precision machined parts*.

These two standards provide a model for aerospace quality assurance in design, development, production, installation and servicing. Compliance with all applicable processes and procedures is mandatory for all personnel. PCB is accredited to ISO17025 by The American Association for Laboratory Accreditation (A2LA). Our Laser Welding process is certified by the National Aerospace and Defense Contractors Accreditation Program (NADCAP). Production Quality Assurance Notification for ATEX and IECEx certification schemes issued by DEKRA (identification number 0344) under ATEX114 and specification IEC80079-34. IECEx Quality Assessment Reporting process is conducted by CSA International.

In addition, the facility complies with ISO10012; ANSI-Z540.3, former MIL-STD-45662A; MIL-Q-9858 and MIL-I-45208. Is a commercial-grade supplier to the Nuclear Power industry in accordance with applicable requirements of 10CFR50 Appendix B and reporting requirements of 10CFR21, and has implemented system requirements providing customers with products compliant to Directive 2011/65/EU regarding restriction of hazardous substances (RoHS) and their disposal. Product Manufacturing Approval (PMA) realized will be in accordance with 14CFR21 and Authorized Repair Station requirements 14CFR145. All calibration standards used within the facility are traceable, at a minimum, to NIST and/or the European PTB Standards Organization.

The ISO-17025 portion of our quality management system provides calibrations performed using processes having a test uncertainty ratio (TUR) of four or more times greater than the unit calibrated, unless otherwise noted on the calibration certificate. Calibration at 4:1 TUR provides reasonable confidence that the instrument is within product specifications.

PCB Piezotronics of North Carolina Inc. Facility located at 10869 Highway 903, Halifax, North Carolina:

The quality assurance system is certified to the International Quality Standards AS9100 and ISO9001, with scope of certification defined as: *The manufacture of sensors and signal conditioning electronics used for measurement of force and vibratory motion*.

These two standards provide a model for quality assurance in design, development, production, installation and servicing. AS9100 Clauses 8.1, 8.2 and 8.3 are not applicable as the Depew, N.Y. location conducts these processes. Compliance with all applicable processes and procedures is mandatory for all personnel. The facility is accredited to ISO17025 by The American Association for Laboratory Accreditation (A2LA). Production Quality Assurance Notification for ATEX and IECEx certification schemes issued by DEKRA (identification number 0344) under Directive ATEX114 and specification IEC80079-34. IECEx Quality Assessment Reporting process is conducted by CSA International. In addition, the facility complies with ISO-10012; ANSI–Z540.3, former MIL-STD-45662A; MIL-I-45208. Is a commercial-grade supplier to the Nuclear Power industry in accordance with applicable requirements of 10CFR50 Appendix B and reporting requirements of 10CFR21, and has implemented system requirements providing customers with products compliant to Directive 2011/65/EU regarding restriction of hazardous substances (RoHS) and their disposal. All calibration standards used within the facility are traceable, at a minimum, to NIST or the European PTB Standards Organization. Calibration at 4:1 TUR provides reasonable confidence that the instrument is within product specifications.

Larson Davis located in Provo, Utah, is certified to ISO9001, ISO17025 and ANSI-Z-540-1 and EN/IEC 80079-34

PCB Load & Torque located in Farmington Hills, Michigan, is certified to ISO9001, ISO17025 and ANSI-Z-540.3.

## 1.7 Financial Information:

Fiscal year is beginning of October to end of September.

Federal Taxpayer Identification Number - Depew: 16-1503703

Federal Taxpayer Identification Number - Halifax: 20-2128287

Duns Number: 04-256-8774

## 1.8 General Information:

Cage Code: 52681

Internet Address: www.pcb.com

E-Mail Address: info@pcb.com

# 2.0 QUALITY POLICY

The president of PCB has selected the following statement to convey the PCB Quality Policy: “It is the policy of PCB Piezotronics, Inc. to do whatever is necessary to realize our vision of ***TOTAL CUSTOMER SATISFACTION***. We have selected this term in the effort to communicate the policy to our customers. Our quality management system measurement metrics ensure the goal and vision of TOTAL CUSTOMER SATISFACTION is consistently achieved.”

The Senior Leadership Team (SLT) is dedicated and committed to the continual improvement of business and quality objectives monitored through measurement metrics which are set and reviewed often for continued relevance and value in realizing our quality policy. The SLT conducts management reviews of the quality system on a periodic basis. These reviews include, at a minimum, measurement metrics of the quality objectives, the results of internal and external audits, customer complaints and their feedback, process and product conformity, recommendations for improvement, corrective and preventative actions, matters arising from previous reviews, reviews of intrinsic safe and explosive atmosphere products, calibration service programs, and status of employee training.

The Larson Davis management team has acknowledged this same quality policy statement. The Quality Policy embodies the corporate philosophy at PCB. Quality of workmanship and service are encouraged without adding unduly to cost. Quality is primarily dependent upon individual commitment and acceptance of responsibility by each employee for the quality of the products and services offered, both internal and external to PCB. Efforts of continuous improvement focus on enhancement of product reliability and customer satisfaction.

The following condensed statement conveys the PCB Quality Policy:

**“Total Customer Satisfaction”**

**Mission Statement:** “Helping you make better measurements with quality, innovative instruments.”

**Vision:** Continuously improve and deliver ***Total Customer Satisfaction*** to consistently provide reasonably priced, quality products on-time to the schedules of our customers.

**Total Customer Satisfaction:** Our policy at **PCB** isto do whatever is necessary to realize our vision of **TOTAL CUSTOMER SATISFACTION**. At PCB, **“Total Customer Satisfaction”** is the essence of how we do business.

In an effort to reach our goal of TOTAL CUSTOMER SATISFACTION, if at any time there is a conflict between the PCB quality management system and customer, statutory or regulatory requirements—the customer or the statutory/regulatory requirements will take precedence.

All PCB personnel are required to understand our goal of TOTAL CUSTOMER SATISFACTION, to familiarize themselves with the required quality management system documentation, and to follow the policies and procedures applicable to their job description responsibilities.

In addition to this general PCB quality policy for both manufacturing and service activities, the senior leadership team is committed to good professional practice and quality of calibration service for our clients. To this end, PCB’s calibration activities shall maintain accreditation with ISO17025 and ANSI-Z540-1.

## 2.1 Quality Objectives and Commitments

These objectives are part of the foundation for the LD Quality Management System.

**Objective:** “Quality as a primary objective through Total Customer Satisfaction”.

Measure: Departmental score sheets; Manufacturing metrics; Customer Satisfaction feedback reports; Warranty returns;

**Objective:** “on time delivery”.

Measure: Monthly on time delivery reports by promise date.

**Objective:** “continuous growth as a % of Goal”.

Measure: Sales growth shipments vs. past years (showing improvement each year)

**Objective:** “scrap as a % of sales”.

 Measure: Scrap rate as a percent of sales numbers.

**Objective:** “provide reasonably priced products”.

Measure: competition price comparisons, discount levels, sales growth/decline, inflation/cogs changes, feedback from sales channels.

**Objective**: “provide innovative products and services that meet customer needs”.

Measure: customer feedback reports; new product releases.

**Objective**: “provide professional operational practices and quality calibration services.”

Measure: Customer feedback for calibration work, ISO17025 and ANSI Z540-1 certification.

**Objective:** “Intrinsically safe products that meet Ex Certificate requirements & market demand.”

Measure: Customer feedback, audits and continued certification to ISO/IEC.

## 2.2 Quality Policy Implementation

The various corporate quality objectives and risk assessment analysis are documented in the controlled agenda and subsequent meeting minutes from the Management Review of the LD Quality Management System. The scheduled reviews are chaired by the Director of LD Operations (DOO)/General Manager (GM) and includes but is not limited to those required areas of review specified in the Management Review procedure, D0001.1164.

The LD management team will meet periodically to identify the risks associated with obtaining the objectives and provide resources and direction to mitigate the risks. This review will be documented on the Management Review Meeting Minutes Worksheet (D0001.1164-2).

The items reviewed satisfy both internal needs and customer expectations.

The Quality Policy, including the Mission and Vision Statements, is reviewed for continued suitability by the DOO/GM as part of the management review process detailed in the Management Review procedure.

## 2.3 Control and Distribution of QMS

Controlled copies of the QMS and other documents are maintained electronically by the Document Control Clerk. Access is available to all employees of the company. New employees are trained on the location and content of the QMS during their introductory training schedule. On-going training of the QMS is conducted by management during routine staff meetings, company-wide meetings and at times when policies and procedures change.

The controlled documents are reviewed and edited as processes change. Changes to the QMS are recommended by QA, the DOO/GM, Department Managers and any employee. The recommendations are approved by QA, the DOO/GM and other department managers via the Document Change Order procedure, D0001.1021. Distribution of the controlled documents is via electronic access. The current revisions are maintained electronically in Document Control and employees are responsible to verify that they are using the current version.

Copies of the “Quality Management System” are for reference only and are not controlled copies (includes versions sent electronically to customers). Uncontrolled copies are not kept up to date. This document is available for distribution to customers as an uncontrolled document and an updated copy can be requested by a customer.

# 3.0 QUALITY MANAGEMENT SYSTEM

## 3.1 General Requirements of the QMS

Larson Davis has established, documented, implemented, maintains, and continually improves its quality management system. Management is directly responsible for the Quality System and the risks associated with setting objectives and maintaining the quality system.

The Quality Assurance (QA) Manager has the responsibility to ensure that the QMS is evaluated through methods that include but are not limited to management review, internal audits, risk assessment, and documentation reviews. The QA Manager reports the results of evaluations, the status, adequacy and effectiveness of the QMS at the Management Review meetings.

Implementation of the QMS includes but is not limited to:

* Identifying the applications and processes needed for the QMS
* Determining the sequence and interaction of those processes
* Determining the criteria, risks and methods required to ensure the effective operation and control of those processes
* Ensuring the availability of resources and information necessary to support the operation and monitor the processes
* Ensuring that monitoring, analysis and measurement of the processes occurs as appropriate
* Implementing those actions that are necessary to achieve the planned results
* Promoting and implementing actions that support continual improvement

Outsourced processes are provided by suppliers including other PCB divisions and departments that have been reviewed by Larson Davis prior to being approved as a supplier of products and services. The details of supplier qualification are contained in the “Purchasing” procedure (D0001.1068) and the PCB QAM 8.4 (to the extent that it is applicable to the Larson Davis purchasing process).

## 3.2 QMS Documentation Requirements

The QMS is approved and reviewed by the DOO/GM. Evidence of the review and approval is documented through the management review process, or approval per the Document Change Order process, D0001.1021 when changes are made to quality documentation.

Upper level procedures are reviewed and approved, at a minimum, by the DOO/GM and the LD QA Manager.

Work instructions are reviewed and approved by those individuals having responsibility for those instructions. Individuals that are required to perform the review/approval include but are not limited to:

* Department Manager
* QA Manager
* Project Engineer
* Technician
* Author of the document

Procedures or work instructions are written to provide additional information for the process. The documents are required when the absence of such documents may affect the quality of the finished product or service. Not all processes require procedures or work instructions. The determination of need is the responsibility of the Department Manager and QA Manager.

Records to be retained are specified in the individual procedures and work instructions. In addition, QA maintains a matrix of records being kept, their retention and where applicable their disposition (see D0001.1126-1).

The extent of the QMS documentation is determined by management to ensure the effective planning, risk assessment, operation and control of processes. The following may be considered when determining the level of documentation:

* The size and organization of the departments
* The complexity and interaction of the particular process
* The competence of the personnel

## 3.3 Definitions

**Approval** – Where the term *approval* is used it refers to official recognition of a process, procedure, change, etc. that is documented by signature, initials or electronically approved by those functions listed as being affected or with responsibility.

**Corrective Action –** An action that is taken to minimize or fix a concern that is affecting processes, procedures, product quality or reliability.

**Document –** Where the word document or documentation is used, it can relate to a text document, drawing or an electronic file.

**DOO –** Director of LD Operations

**GM –** General Manager

**LD Management Team –** Those individuals with authority as specified Section 1.1. When the term “LD Management” is used it typically refers to the member of management with responsibility for the indicated task, function or project.

**LD –** Larson Davis a Division of PCB Piezotronics Inc.

**Preventive Action –** This is an action that prevents a problem from developing.

**PCB –** Generally refers to Larson Davis division but may also refer to the legal entity of the company which includes the LD division.

**QA –** Quality Assurance

**QMS -** Quality Management System, this document may also be referred to as the Quality Manual.

**Responsibility –** Where the phrase “*is responsible for”* or similar phrasing is used; it implies that the position holder or their delegate undertakes the required action, and that each has the authority to undertake the assigned task.

**Risk Assessment—**the process of determine why an objective or commitment many not be met. A process for providing resources to assure objectives and commitments are met.

**Senior Leadership Team (SLT)—**those Vice Presidents, Directors, General Managers that report directly to the President of PCB Piezotronics Inc.

**Sign-off or Signature –** terms used to indicate approval by the individual with responsibility. Sign-off is provided electronically, through routing, verbally, initials or by signature.

## 3.4 Quality Manual

The Quality Management System consists of several levels of documentation. The upper level of documentation is broad and general in its application. This document is an upper level document and is sometimes referred to as the Quality Manual. The Quality Manual provides an overview of the quality system. It defines our quality policy and objectives; the senior leadership team’s commitment to quality and the identification of our processes. The manual is revised accordingly to keep current with our processes as they are continually improved. Quality Manual revisions are maintained by an electronic document control system. Access to this documentation is made available to all employees, at all facilities involved in operations essential to the effective functioning of the system, through shared drives on the company network. Printed copies are considered uncontrolled documents.

Procedure and Process documentation is more detailed in its scope and application. Depending on the purpose of the process or procedure, documentation of sufficient detail may be included to allow its use as a work instruction.

Work Instructions are the most detailed and specific documentation. These documents are the "How it is done" instructions. Work instructions written prior to January 1st, 2002 are used in their current form until re-written or made obsolete by the responsible department. Documents written after January 1st, 2002 are written, numbered, approved and controlled by Document Control. Work Instructions that are specific to the quality system are referenced in the related process / procedure level documentation.

Records are the documentation that is used to demonstrate compliance, completion or other required information from the processes, procedures or work instructions.

**QUALITY**

**MANAGEMENT SYSTEM**

**POLICIES, PROCESSES & PROCEDURES**

**WORK INSTRUCTIONS, FLOW CHARTS**

**RECORDS, OTHER DOCUMENTATION**

DETAIL INCREASES

## 3.5 Quality Processes

**Leadership Commitment**

Quality objectives, Goals, & Commitments, External & Internal Communication, Strategic Planning, Quality Policy, Management Review, Customer Focus, Risk Assessment, Resource Commitment to Improvements

**Resource Management**

Human Resources, Work Environment, Employee Competence, Training, Communication, Documentation, Facilities Management, Facilities & Equipment Maintenance, Information Technology

**Performance Evaluation & Improvement**

Customer Satisfaction, Customer Communication, Internal Audits, Product Test, Non-Conformant Materials, Monthly Reports, Engineering Change Order, Document Change Order, Corrective/Preventive Action Process, Calibration System, Management Reviews and Improvements

**Product Realization & Operations**

Product Requirement/Specifications, Product Validation, Product Verification, Industry Standards, Design & Development, Product Conformance, Purchasing, Supplier (parts/materials), Supplier (processes), Non-conformant Materials, Incoming Inspection, In process Inspection, Final Inspection, Product Identification & Traceability, Contract Review, Quotes, Product Verification, Product Preservation, Customer Communication, Control of Customer Supplied Product, Calibration System Controls

### Quality Objectives

1. Quality as a primary corporate objective - Total Customer Satisfaction
2. On time delivery
3. Continuous growth of Larson Davis
4. Provide reasonably priced products
5. Provide innovative products and services
6. Professional operational practices and quality calibration services
7. Intrinsic safe products that meet Ex Certificate requirements and market demand
8. Job training

## 3.6 Document System and Control

The processing and control of documentation is detailed in the Document Control System, procedure D0001.1017. The procedure details but is not limited to the following processes:

* Document approval prior to issue
* Review, approval and update of documents
* Identification of changes and revision status
* How documents are made available to employees
* Protection of documents
* Identify how reference documents including external documents are controlled, distributed and maintained for use in controlling the QMS
* Prevention of unintentional use of obsolete documents
* Instructions for identifying obsolete documents

## 3.7 Control of Records

Records are established to provide evidence of conformance to the various standards or specifications that Larson Davis chooses to meet. The records are maintained in a manner that allows for protection from damage, preservation of legibility and ability to retrieve.

The process for controlling and preserving quality records is detailed in the Quality Records procedure, D0001.1126. D0001.1126-1 is a matrix that provides the details as to:

* What records are kept
* Who has responsibility for their retention and protection
* How they are stored
* How long they are kept
* Who has access
* How the records are disposed

## 3.8 Accreditation and Registration Body—Logo and/or Marking Controls

This section defines requirements for the use of any Quality Management System Registrar, Accreditation Body or similar firm whereby the use of their logo, marking or related terminology must demonstrate compliance to documented guidelines.

Calibration certifications and reports must follow the registration or accreditation body guidelines. For example use of the A2LA logo and markings must be within the scope of accreditation and will use the “A2LA accredited” logo accompanied by the A2LA certificate number. For calibrations outside the scope, certification documentation will not display the A2LA logo but may reference the certificate number as a resource for our customers. Applications in this regard will be confirmed for compliance to Registrar and Accredited Body guidelines prior to use by the Quality Assurance Manager as described in D0002.0005.

Marketing and advertisement medium involving use of a Registrar or Accreditation Body logo and/or grammatical statement will be used as credential information specific to the PCB facility identified on the scope of accreditation and/or certification. Product-specific information will be verified to current scope of accreditation by the Marketing Department prior to the use of subject information. Proposed use of this information may be submitted for compliance review to the Quality Assurance Manager as deemed necessary by the Marketing Department.

# 4.0 CONTEXT OF THE ORGANIZATION

## 4.1 Understanding the organization and its context.

 The president and senior leadership team have documented the external and internal issues relevant to PCB’s purpose and strategic direction, and their affect upon our ability to achieve the intended results of our quality management system. The President and senior leadership team monitor and periodically review our policy metrics addressing these external and internal issues. This review ensures that our quality policy of “Total Customer Satisfaction” and corresponding mission statement “Helping You Make Better Measurements with Quality, Innovative Instruments”, are monitored for performance by quality objective trend data through senior leadership team meetings, management review meetings, and departmental meetings where policy metrics support the higher-level corporate quality objectives.

## 4.2 Understanding the needs and expectations of interested parties.

Due to their effect or potential effect on the organization’s ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, LD has determined:

1. The interested parties relevant to our quality management system (e.g., customer, supplier, employee, shareholders) are documented and retained using the Management Review Meeting Minutes form D0001.1164-2.
2. The requirements of interested parties that are relevant to our quality management system as defined on form D0001.1164-2.

LD monitors and reviews these relevant requirements for interested parties on an ongoing basis.

## 4.3 Determining the scope of the quality management system.

 The president and senior leadership team have identified the boundaries and applicability of our quality management system to established the scope. The scope considers external and internal issues, requirements of relevant interested parties, and the products and services of the company.

## 4.4 Quality management system and its processes.

**4.4.1** LD has established, implemented, maintains, and continually improves the quality management system, including the sequence of processes and their interactions, in accordance with ISO 9001 and applicable statutory and regulatory requirements. LD has identified the processes needed for the quality management system and their application within the organization. Processes identified and defined throughout this manual address:

1. Inputs required and outputs expected
2. Sequence and interaction
3. Monitoring and measurement of performance indicators ensuring effective operation and control
4. Ensuring availability of required resources
5. Responsibility and authority
6. Risks and opportunities
7. Implement changes needed to ensure intended results are achieved
8. Improving processes and quality management system

 LD has established and maintains a Quality System Manual (QSM - Level I) that includes the scope of the manual and details for any exclusion. The Quality System Manual references corresponding Level II process procedures describing the interaction between processes and facilities. Documented process procedures directly relate to incremented individual requirement clauses of applicable International Standards and other corresponding regulatory documents.

 Level III work instructions, flowcharts and user guides are used where the absence of such documents could adversely affect quality. These documents are kept current to maintain their continued suitability and relevance. Management utilizes internal and external audits for ensuring current and effective quality system documentation. The Quality Assurance Manager has the ultimate responsibility to ensure that the Quality Management System is implemented, understood and maintained at all levels of the organization.

 This Quality Assurance Manual and Controlled Department procedures define the LD requirements and plans for quality. The interaction of the Senior Leadership Team, Technology Centers / Divisions, Functional Support Departments, as well as additional assigned responsible employees defined in procedures; provide methods for meeting our stated quality policy, objectives and continuous improvement requirements.

**4.4.2** LD maintains and retains, to the extent necessary, documented information to support the operation of our processes and that they are being carried out as planned.

LD has established and maintained documented information including:

1. A general description of relevant parties within the Level II documentation
2. Scope of the quality management system including boundaries and applicability
3. Descriptions of processes of the quality management system and their application
4. Process sequence and interaction
5. Process responsibility and authority

 For product certified to Intrinsic Safe standards such as ATEX and IEC80079-34, LD has defined the necessary quality management system processes needed to ensure that product requirements as described in the EC-Type Examination Certificates are realized (See D0001.0014 Quality Addendum for Intrinsic Safe Products).

# 5.0 LEADERSHIP

## 5.1 Leadership Commitment

Management demonstrates their leadership and commitment to our QMS by verifying the effectiveness of our quality management system to fulfill the stated policy of “Total Customer Satisfaction”, in the following ways:

* Establishing a quality policy, Vision and Mission Statements and ensuring that objectives are compatible with our strategic organizational direction.
* Integrating our QMS into our organizations business plan.
* Promoting a process approach and risk based thinking.
* Providing the resources necessary to research regulatory & statutory requirements as part of the design process.
* Communicating the importance of our QMS requirements and achieving planned results.
* Ensuring the availability of necessary resources, i.e., financial, human, training, equipment and infrastructure.
* Participation in management reviews of the QMS (Management Review, (D0001.1164-2).
* Promoting improvement and supporting relevant management roles demonstrating effective leadership.

Management conveys the importance of meeting customer, statutory and regulatory requirements through posting of its Quality Policy and Mission Statement throughout the company facilities. Additional posting of various internal measures in support of our policy metrics and departmental goals aid in the communication of these requirements to all employees.

Operational integrity of the QMS is ensured by maintaining a trained and internally staffed auditing process that continually verifies the effectiveness of the QMS.

### 5.1.1 Customer Focus

 The management team demonstrates leadership and commitment by ensuring that:

* Customer and applicable statutory and regulatory requirements are determined, understood and consistently met
* Risks or opportunities which may affect conformity of products or services or enhance customer satisfaction are implemented
* The maintaining of customer satisfaction, monitoring product or service conformity and corresponding on-time delivery
* Ensuring appropriate action is taken if planned results are not, or will not be, achieved

Larson Davis publishes printed datasheets and provides product information on our website that customers can use to determine if a product meets their requirements. We further offer email and phone support where customers can review requirements with LD personnel to verify that provided items will meet their requirements. Larson Davis reviews orders and quotes and where there is an identified risk that the items quoted or ordered may not meet customer requirements the order is reviewed with the customer prior to accepting the order. The contract review process is performed by PCB Sales division which is audited to AS9100 and ISO9000 standards by the PCB external auditor. Customer needs, both desired and regulated, will be part of management’s risk assessment planning and documented on the risk assessment worksheet.

Larson Davis is committed to doing whatever is necessary to provide total customer satisfaction.

## 5.2 Policy

### 5.2.1 Establishing the Quality Policy

The senior leadership team has established, implemented, and maintains our quality policy “Total Customer Satisfaction” that is appropriate for our purpose and organizational context and strategic direction. This policy provides the framework for our quality objectives defined in the quality manual, and includes the commitment to satisfy all applicable requirements and continually improve our quality management system.

In addition, the senior leadership team has selected the following mission statement: “Helping You Make Better Measurements with Quality, Innovative Instruments.” in support of our quality policy. The Quality Policy and Mission Statement are posted at numerous locations throughout the company, and are periodically reviewed during training for newly hired persons and also during employee performance reviews. The Quality Policy and Mission Statement are also reviewed for continued suitability during each Management Review meeting.

Management determines the goals and measurement guidelines for the Quality Policy objectives. The risks associated with these goals are also noted and a person is assigned to monitor mitigation plans to reduce risks. The measurements used to gage how Larson Davis is meeting its objectives include but are not limited to these key performance indicators (KPI):

* Percent of On-time deliveries
* Percent of Sales goals being met
* Quality at the customer including warranty return rate as a percent of sales
* Vendor On-time delivery
* Inventory control and cycle count reports
* First pass test at Technician area
* Final inspection failures
* Non-Conformance Reports (NCR)
* Scrap and rework metrics

The compiled results of the methods used to measure quality are reviewed by Management as part of the management review to determine company performance and to identify areas for improvement.

The QMS uses quality-planning tools to ensure that the necessary processes and procedures are in place to:

* Further the goals of the company
* Produce products
* Provide Total Customer Satisfaction
* Reduce risks of not obtaining objectives

Necessary changes to the QMS are made in a controlled manner to allow the changes to be incorporated into the quality culture and to preserve the integrity of the quality system.

### 5.2.2 Communicating the Quality Policy

The Quality Policy—“Total Customer Satisfaction” is communicated to employees and appropriate relevant interested parties via this document; through inclusion in the “Employee Guidebook”, and postings of our Quality Policy throughout our facilities. Employees are required to know how their job responsibilities support our quality policy and quality objectives.

Management communicates the status and effectiveness of the quality system with the employees. The process of communication can occur through any methodology including but not limited to:

* Informal meetings (i.e. DONUT day – Distribution of Official News, Updates & Training)
* Formal Company meetings
* Posting on company bulletin boards and intranet sites
* Department meetings
* Memos, emails, etc.

## 5.3 Organizational Roles, Responsibility and Authority

The LD DOO/GM has ultimate responsibility for quality in the Larson Davis Division. The DOO/GM may appoint other managers to assist and carry out the day to day management of the QMS. The responsibilities include but are not limited to:

* Ensure that those processes identified as part of the QMS are established, implemented and maintained to company goals and international standards organizations.
* Ensure that processes are delivering their intended results.
* Ensure customer awareness throughout the organization.
* Report to corporate management on the performance and status of the quality system and that intended results are obtained.
* Make recommendations for quality improvements.
* Interface with the other PCB corporate quality personnel so as to keep quality objectives consistent throughout all divisions of the company.
* Ensure the integrity of the QMS when changes are planned and implemented in an orderly manner.

Larson Davis has documented its various job functions by way of written job descriptions. The job description details what the requirements are for the position (training, education, etc.) and the responsibilities of the job function. The process governing the creation of job descriptions is the Job Description Policy, D0001.1004. The employee job description responsibilities and corresponding work instructions define the methods by which they support and serve the customer’s needs. A senior leadership team member, operations manager, or department supervisor support each employee.

The inter-relationship of the job functions and employees is graphically depicted in the Company Organization Chart. The organization chart is the responsibility of the Human Resource Department per the Organization Chart procedure, D0001.1003.

The senior leadership team has provided each employee with the organizational freedom to complete an appropriate corrective action form to address product, process or service issues that are contradictory to the philosophy and requirements of the QMS.

Product management is provided by the applicable company technology center consisting of individuals from Sales & Marketing, Engineering and Manufacturing Departments. These employees are responsible for managing all product related planning, development, production, application, support, servicing and quality. The Quality Committee is responsible for ensuring that company-wide corrective and preventive measures support continuous improvement and are addressed effectively through the use of root cause analysis. Internal Auditors are responsible for ensuring continued compliance to all relevant documents (nationally or internationally recognized standards listed above) for which the QMS is accredited, registered or compliant with in accordance with planned arrangements defined in the internal Audit Schedule.

**Other relevant responsibilities include:**

1. President: responsible for all corporate strategic planning and direction.
2. Senior Leadership Team: responsible for ensuring all corporate strategic goals and quality management system requirements are consistently fulfilled.
3. Sales Staff: Responsible for all facets involving developing objectives, strategies and programs for sales and marketing activities. Also customer relations and ensuring continued compliance to customer contractual requirements.
4. Manufacturing: Responsible for all facets of product, processes and services as well as development, implementation and compliance to systems affecting product quality, cost, delivery and the corresponding infrastructure requirements for equipment and personnel.
5. Finance: Responsible for corporate financial policies and oversees all financial functions including accounting, budget, credit, insurance, tax and treasury.
6. Quality Director: Responsible for implementation and maintenance of the TCS quality management system and continuous improvement programs.
7. Sales Manager: Responsible for implementation and support of Sales directives.
8. I.T. Director: Responsible for all Computer and Network functions.
9. Engineering Manager: Provides support and technical direction for engineers.
10. General Counsel: Responsible for review and compliance of all contractual and regulatory requirements.
11. Intrinsic Safe Products Manager (ISP): Responsible for representing LD as point of contact for product manufacturing systems where product certified to ATEX (IEC80079-34) for use in potentially explosive atmospheres is produced. Ensures effective coordination of activities with respect to products intended for use in potentially explosive atmospheres. Responsible to liaise with the Notified Body responsible for the issue of the EC Type Examination Certificate with respect to any proposed change to the design defined in the EC Type Examination Certificate and technical documentation. The ISP Manager is responsible for the authorization of initial approval and changes to related drawings as appropriate, and concessions as well as informing the customer of any applicable special conditions for safe use or schedules of limitations (see note 1 and 2 of section 5.5.1 IEC80079-34).
12. Quality Assurance System Manager: Implementation and maintenance of the quality management system, corrective and preventive action programs, statistical practices and continual improvement of systems and products. Provides support and direction to quality assurance department staff. Responsible for contacting the Notified Body(s) for coordination of required assessment regarding changes to the Quality Management System (QMS). Also QMS changes that effect products certified to ATEX (IEC80079-34) or systems resulting from revisions or updates of applicable Standards or updates to the Quality Assurance Notification due to the addition or removal of an EC-Type Examination Certificate.

# 6.0 PLANNING

## 6.1 Actions to Address Risks and Opportunities

**6.1.1** Our quality management system considers the context of our organization and the associated risks and opportunities that need to be addressed to ensure our quality management system can achieve its planned results. Planning of the quality management system takes place through senior leadership team and management review meetings. Evaluation of the documented information includes enhancing desired effects, preventing or reducing undesired effects and achieving continual improvement.

**6.1.2** Quality management system planning includes actions to address risks and opportunities, and how to integrate, implement, and evaluate these actions for effectiveness. Actions taken to address risks and opportunities are proportionate to the potential impact on product or service conformity. The senior leadership team has identified the following as acceptable examples of monitoring risks and detecting opportunities for improvement:

1. Production technician training
2. Lean manufacturing processes
3. Core competency training as outlined and expressed in job descriptions
4. Key production Indicators (KPI)
5. Product launch processes (D0001.1009)
6. Customer complaints (SM012)
7. Internal and external audit findings (D0001.1166)
8. Inspection department records (D0001.1126)
9. Customer Service Feedback and survey information trends - Total Customer Satisfaction (SM1031)

Determining causes of potential nonconformities during the design stage of new products, the responsible design team may require Design of Experiments (DOE) or Design Failure Mode and Effects Analysis (DFMEA) or other methods as indicated within design records; in the event that current documented best design practices and associated risk information is considered insufficient. Acceptable levels of risk shall be determined by the Design Engineering Team Leader and with process oversight by Engineering Management. Subsequent required actions are conducted and records maintained during project reviews. Engineering management confirms effective preventive actions are employed during departmental and/or project review meetings.

Determining causes of potential nonconformities for products released to manufacturing is conducted by engineering. Manufacturing policy metric reviews document product trends and any actions taken. A Process Failure Mode and Effects Analysis (PFMEA) may be conducted at the request of manufacturing management.

## 6.2 Quality Objectives and Planning to Achieve Them

### 6.2.1 Establishing Quality Objectives

Quality objectives have been established by corporate, senior leadership team, divisional and departmental areas for the quality management system. Our quality objectives are consistent with our quality policy “Total Customer Satisfaction”. These objectives are:

1. Measurable
2. Account for applicable requirements
3. Relevant to the conformity of our products and services which enhance customer satisfaction
4. Monitored
5. Communicated
6. Updated when needed

Contributing to and in support of these metrics are product related requirements, implemented at relevant department levels within the company (departmental procedures and work instructions), that satisfy the Total Customer Satisfaction quality policy.

Our quality policy objectives are:

1. Quality as a primary corporate objective Quality at the customer (ppm) - Total Customer Satisfaction
2. On time delivery %
3. Continuous growth—Shipments as a % of Goal
4. Scrap as a % of Sales
5. Provide reasonably priced products
6. Provide innovative products and services
7. Professional operational practices and quality calibration services
8. Intrinsic safe products that meet Ex Certificate requirements and market demand
9. Job training

When planning for the conformity of products, processes, or services, LD considers the following activities, as appropriate:

1. New Model Instructions
2. Engineering Design Folders
3. EC Type-Examination Certificates when required
4. Design Drawings
5. Bills of Materials
6. Assembly Procedures
7. Production Routers
8. Test Procedures
9. Product Specifications
10. The identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve required product quality.
11. Ensuring the compatibility of the design, production process, installation, servicing, inspection and test procedures and the applicable documentation (see D0001.1009).
12. The updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation (see D0001.1009 and D0001.1112).
13. The identification of suitable verification at appropriate stages in the realization of product (see D0001.1112 and D0001.1116).
14. The clarification of standards of acceptability for all features and requirements, including those that contain a subjective element (see D0001.1009).
15. The identification and preparation of quality records (see D0001.1126) and departmental quality record matrices.

For explosion-proof certified products the Notified Body may audit any aspect of our organization that affects the type of protection.

### 6.2.2 Planning to Achieve Quality Objectives

The planning for achieving our quality objectives includes what will be done, resources required, responsible parties, completion time and how results will be evaluated. The integrity of the quality management system is maintained when any changes occur by way of the defined procedure for issue and release of quality management system documentation (see D0001.1021 and D0001.1022).

Operational integrity of the quality management system is ensured by maintaining an adequately trained and staffed internal auditing process that continually verifies the effectiveness of the quality management system (see D0001.1166). Additionally, the strategic aspect of the quality system is maintained by regular communications between the LD management and the senior leadership team through scheduled meetings.

## 6.3 Planning of Changes

When it is determined that our organization needs to revise or change our quality management system, the actions are carried out in a planned manner. This process considers the purpose of the change and relevant potential consequences, the integrity of our quality management system, availability of resources, and the assigning of responsibilities and authorities. These changes may be scheduled and assigned during Management Reviews of the QMS or other appropriate times.

# 7.0 SUPPORT

## 7.1 Resources

### 7.1.1 General

Internal and external resources needed for the establishment, maintenance and continual improvement of the quality management system are evaluated for capabilities of and constraints on existing internal resources. Management provides this oversight to:

* Enhance customer satisfaction by meeting the customer’s requirements
* Implement and maintain the QMS
* Continually improve the effectiveness of the QMS

The resources required are reviewed as part of the management review and as part of the implementation of the strategic plan. Outputs from the reviews as well as decisions made based on policy metrics and other management meetings document the results for provisions of resources.

Resources include but are not limited to:

* Personnel—competence and training
* Infrastructure
* Work environment for processes—equipment & tools
* Implementation of new processes

### 7.1.2 Human Resources

Management shall ensure that the company hires, trains and evaluates personnel sufficient to meet the objectives of the company. Management recognizes that all personnel who perform tasks within the quality management system will affect quality of product directly and indirectly. Employees are trained on the quality system so that they understand their performance directly impacts the effectiveness of the QMS. With proper training employees can understand the positive and detrimental impacts they may have of not conforming with QMS requirements.

Procedures have been written to govern job descriptions, training and performance evaluations with the quality objectives in mind and to ensure that each employee understands the role they play in meeting the quality objectives of the company and for the operation and control of its processes.

Human resources necessary for the effective operation of our quality management system and the operation and control of our processes are provided. For every manufacturing or inspection activity, operators:

1. Verify that documentation corresponds with part(s) in process and legibly complete all paperwork.
2. Verify that equipment and instruments are in good working order and are within their calibration cycle.
3. Assure work instructions are understood (if the instructions are unclear or cannot be followed, employees are to obtain any necessary clarification from their supervisor).
4. Identify and segregate nonconforming materials per D0001.1034 Non-Conforming Materials and D0001.1023 Waiver Procedure.

Suitable production, installation and servicing equipment are provided to ensure product quality. A suitably lighted, clean and safe work environment is maintained.

1. Equipment is appropriately stored and adequately protected between use and calibration.
2. Equipment is verified at defined intervals./
3. The ESD Procedure, D0001.1102, is understood and followed.
4. No operations will be performed until questions regarding safety are resolved.
5. Personnel are responsible for the cleanliness of their immediate work area.
6. Environmental conditions for manufacturing and test areas in accordance with ISO/IEC 17025 are defined; employees should notify management when conditions are not in accordance with stated parameters.

The hiring of personnel is determined by management. The “Hiring & Applicant” procedure, PE1003, is used to recruit, hire and evaluate new personnel.

The prospective employee is evaluated per the requirements of the position. The type of information contained in the job description is specified by the Employee Job Description procedure, D0001.1004.

Employee training needs are determined prior to hiring using the Training System procedure, D0001.1005.

Employee performance is evaluated throughout the year by way of the performance review process. The review is conducted by the employee’s supervisor or manager. Supervisors and managers follow the performance review policies established by management and Human Resources and referenced in PE1000-LD and specified for the class of employees in PE1010. Training records are maintained by corporate human resources. Managers are informed when new procedures are released or existing procedures are changed so that employees affected by the change may receive proper training.

The effectiveness of employee training and knowledge acquisition of the company operations and processes necessary to achieve conformity of the company products and services is determined through a variety of methods in addition to performance reviews. The methods used are at the discretion of the DOO/GM, the trainer, or the supervisor. Methods used to evaluate potential employees knowledge, skills and employee training effectiveness can include but are not limited to the following:

* Testing
* Pass / Fail percentages
* Observation

If training is shown ineffective with an employee, the training process is reviewed and the employee re-trained. The effectiveness of the repeated training is then evaluated.

### 7.1.3 Infrastructure

During Management Review (D0001.1164), the Management Team will review policy metrics to determine and ensure necessary sustained infrastructure aimed at enhancing Total Customer Satisfaction and product conformity. Continued compliance with customer, statutory and regulatory requirements, is accomplished by regularly evaluating quality management system processes, personnel and equipment, to ensure effective quality management systems are continued suitable for providing conforming products, processes, or services. Evaluation criteria may be in the form of training reviews, internal and external audit results, warranty returns, quality concerns, sales trends and other reports that show manufacturing trends.

LD determines, provides and maintains the infrastructure required to achieve conformity to product requirements. Information obtained for review and planning may be in the form of daily manufacturing reports that include information such as, but not limited to: Sales Orders, Production Projects, Engineering Requests/Prototypes, and Customer Requests. Management may also use information input from the corrective action system, strategic plans, audit results, Safety Committee minutes, productivity and efficiency reports, and will maintain the proper infrastructure in support of “Total Customer Satisfaction”. These manufacturing reports are available to all departments.

The management team is responsible for continued relevance and maintenance of the facility, work environment, software/hardware equipment, transportation resources, information and communication technologies, buildings and associated utilities. This is provided by and through management review and management quality & organizational meetings.

The management team and department managers are responsible for maintaining adequate process equipment, including hardware and software. Processes are controlled and approved by managers (in accordance with signing authority policies), operations managers and department supervisors. Newly acquired equipment is verified and approved prior to use. Types of verification may include preventative maintenance, calibration, or set up verification per manufacturer’s recommendations. Where the absence of procedures will adversely affect product quality, each department is responsible for providing, documenting and maintaining work instructions for use as criteria for performing production operations.

The Information Technology (IT) group maintains the electronic hardware for electronic data transmission and telephone conversation. IT also ensures the security of the electronic data. The IT procedure that relates to infrastructure is the IT – Systems & Data Integrity procedure, D0001.1008. The IT services are managed and controlled by corporate procedures.

Preventive maintenance is part of ensuring product quality. The Equipment Maintenance – Manufacturing procedure, D0001.1090, is part of the preventive maintenance program at LD.

### 7.1.4 Environment for the Operation of Processes

The work environment is maintained to be clean and free of hazards that have the potential for damaging product or personnel and interfering with conformity of company products and services. The typical work environment temperature is maintained between 55° and 85° Fahrenheit. The relative humidity (RH) is the ambient RH and is dependent on the weather and season of the year. The relative humidity in areas of the production facility is to be maintained between 25% and 50%. Products requiring testing in a wider range of environments or under controlled conditions are tested in environmental chambers and rooms that are maintained for the required testing.

Employee health and safety is considered when making changes to the work environment including the addition of new processes or methods. Environmental conditions such as noise in the work place, lighting and weather related factors are considered and monitored to assure the best environment for employee health, safety and product quality realization. Employee Guides contain policies regarding Non-Harassment in the Workplace, General Code of Conduct, Code of Ethics, Safety Policy and others designed to help maintain a safe work environment for all employees (also see PE2016-LD).

### 7.1.5 Control of Monitoring and Measuring Resources

Measurement traceability is a significant part of our process that provides confidence in the validity of measurement results and of our measuring equipment. Equipment is calibrated or verified prior to use as defined within our Calibration System Controls (CSC) procedures D0002.0001 and D0002.0004. Measurement standards used are traceable to NIST and other international standards; in the event no such standard exists, the basis used for calibration or verification is retained as controlled documented information. Equipment identified within the CSC is safeguarded from adjustments and/or damage and/or deterioration that may invalidate calibration status and subsequent measurement or verification results.

Monitoring and measuring equipment required for calibration or verification is maintained as noted in the Calibration System Controls procedure (CSC). All monitoring and measuring equipment including equipment type, asset number identification, location, calibration frequency, calibration or verification method and corresponding acceptance criteria is identified and tracker per instructions in D0002.0004. Monitoring and measuring equipment can include test hardware, test software, automated test equipment (ATE), and company designed equipment.

###  7.1.5.1 General

Engineering determines the types of equipment necessary to provide the evidence of conformity for a product being tested or verified. Engineering specifies the measuring equipment, how and when they are used.

Measurement & Test equipment is calibrated or verified, or both, at specified intervals, or prior to use as noted in the database programs. Equipment is tracked by make, model and serial number whenever possible. If the equipment does not have these identifiers then a number is assigned to track the equipment. The database where this information is stored is updated as needed by trained personnel. The calibration / certification information and calibration results for the active equipment are maintained by the QA Manager or designee and stored electronically in Document Control. Instruments requiring calibration prior to use are noted in the work instruction for the process using that instrument.

###  7.1.5.2 Measurement Traceability

Measurement traceability is a significant part of our process that provides confidence in the validity of measurement results and our measuring equipment. Equipment is calibrated and verified prior to use. Equipment is calibrated or verified against measurement standards that are traceable to NIST or an equivalent standards body. If a standard does not exist then the basis for the calibration or verification is recorded as a controlled document.

Calibration status of the measurement equipment is identified on the unit, in the database, in the QC Certification Monitoring spreadsheet or for ISO 17025 standards, procedure D0002.0023. If equipment is found to be out-of-tolerance at or before the end of the scheduled calibration interval, the following actions are taken:

* The equipment is quarantined and removed from service pending review and/or repair.
* Before & after test results of the equipment are reviewed.
* Effect of the out-of-tolerance condition is reviewed for its effect on product types that it is used to test.
* If the out-of-tolerance condition adversely affects customer units then a list of affected customers is generated and the customer(s) contacted.
* If the out-of-tolerance condition is in a range or feature that is not used for calibration or verification activities, the condition is documented and a note is attached to the equipment calibration certificate granting approval for continued use or the approval is indicated on the certificate by the initials of the authorizing individual and the date approved.

Computer software used as part of the measurement and test process is verified by engineering for its intended use prior to implementation. Changes to the function of the software are evaluated and suitability re-evaluated as part of the Engineering Change Order process, D0001.1022.

Adjustment or re-adjustment of the equipment is permitted as long as the adjustments do not invalidate measurement results.

Equipment that is used for test and measurement is protected from damage and deterioration during handling, maintenance and storage.

LD maintains a calibration laboratory that complies with ISO17025 and ANSI Z540-1. The procedure that establishes the systems and process for running this laboratory is D0002.0001.

## 7.1.6 Organizational Knowledge

Organizational knowledge is knowledge specific to our organization; it is usually gained through experience and is used and shared to achieve our quality objectives. The knowledge necessary for the effective operation of our processes, and to achieve conformity of products and services, are maintained and made available to relevant persons through our quality management system. This knowledge is also contained in: intellectual property, knowledge gained from experience, and the results of process, product or service improvements.

The management team considers our current knowledge, and also how to acquire or access any necessary additional knowledge and required updates as the method to addressing changing needs and trends.

Design Control Procedure (D0001.0009) provides knowledge of product development, the development process, or service requirements based upon lessons learned and also changing needs and trends within our industry.

Policy metrics provide knowledge of latest product or service conformity trends and resulting improvements.

## 7.2 Competence

LD has determined the necessary competence of our employees performing work that affects the performance and effectiveness of our quality management system. In the event the necessary competence is acquired externally, the effectiveness of the acquisition is evaluated through periodic performance reviews. Job Description requirements define the required knowledge and parameters for each job title and detail the training and experience required to perform the job. If employees do not meet the minimum requirements, their equivalent experience or other rationale is documented and retained in the employee file.

1. Newly hired employees receive the "New Hire Orientation Program" training (PE02) coordinated by the Human Resources Department. This orientation includes at a minimum: presentation of the Employee Guide, Job Description, Safety Information, 10 CFR 21, and the Confidentiality Agreement Employee Notice. The PE002 Orientation Checklist is completed to record orientation activities. The new hire also reviews the relevant Training Program for their respective job classification maintained in the Human Resource Training Database. Any significant training achievements prior to hire are recorded on the employee’s application or resume and are stored in the employee’s HR file.
	* 1. Upon completion of the new hire orientation training, the employee will also complete the Quality System Overview training program. The Quality System Overview training program is maintained in the HR training database. Training is conducted and documented on the PE003 PCB In-House Training Record Form.
		2. Upon completion of new hire orientation training, the employee will complete their training per the documented training program required for the respective job position, as maintained in the training database. Training new or revised documents shall be in accordance with PE01 and PE1015 (See D0001.1005-4 Training Needs by Job Title).
2. The Human Resource department informs Managers/Supervisors/ Training Committee (QA001) of required training due via a distributed report produced from the training database. The Human Resource department may also provide trainers with a PE003 form that will indicate which employees are identified as requiring training.
3. Required training to special processes, workmanship standards, assembly and/or calibration work instructions are coordinated by the department manager. Continued monitoring of these skills and others are through annual performance reviews conducted by immediate managers or supervisors.
4. Employees transferred from one department to another, must be trained and qualified to the program for that job description prior to performing any work affecting quality. The Human Resources Assistant, according to the new position title, will update the employee’s training program.
5. Evaluation of necessary competency of employees, as a means for continually improving training needs and job description requirement parameters, is documented and demonstrated through performance reviews, policy metrics and quality concerns. Department manager/supervisors review employees with unsatisfactory performance, as required, and document the deficiency and subsequent corrective action in the applicable corrective action record (e.g. Human Resource employee file).
6. Employee files consisting of records for training, education, skills, experience, and job descriptions are maintained by the Human Resource Department per CS002 Document Index.
7. When training is obtained from sources outside of LD certificates or letters indicating attendance are forwarded by the department manager/supervisor to the Human Resources Department for the employee's file.

## 7.3 Awareness

LD’s quality management system ensures that persons doing work under our control (either at our facilities or through a purchase order) are aware of our quality policy “Total Customer Satisfaction”. All personnel must be aware of how their functions contribute to the documented quality objectives and our organizational goals. Internal and external auditing periodically confirms effectiveness of this process. Department Manager/Supervisors assure that scheduled training is completed using the periodic reports generated per PE01.

## 7.4 Communication

The management team identifies internal and external information relevant for the effective operation of our quality management system. The management team then determines what, when, how, with whom, and who will provide effective communication of the information. Effective communication within the organization may take place through documented procedures, policy metrics, management review actions taken, organizational meeting minutes and announcements provided by the president and/or human resource department.

## 7.5 Documented Information

### 7.5.1 General

LD’s quality management system (TCS) includes documented information required by the ISO9001 standard, as well as other standards required by customers or other external interested parties. This documented information has been determined by the senior leadership team as being necessary for the effectiveness of our quality management system. This information includes:

**Level I** - **Quality Management System Manual (QMS)** **–** (sometimes referred to as the Quality Policy Manual): Contains our quality policy “TOTAL CUSTOMER SATISFACTION” and associated mission statement. This document represents the philosophy that embodies the PCB corporate structure and its employees. The Director of LD Operations/GM or his designee (Quality Control Manager) controls and maintains this document. This manual is made available externally upon request to provide an overview of our quality management system and our quality objectives. It is available to employees, who remain familiar with its content, through viewing access on the information systems network. This document indicates the relevant Level II supporting documents.

**Level II – Policy and Procedures –** These documents are available in Document Control, a company-wide electronic document viewing system complying with the requirements of the ISO 9001 Standard as well as additional applicable standards defined in this procedure. The system documentation provides procedures that form the basis of the LD Quality Management System. This documentation is suitable for ensuring effective planning, operation and control of processes and their documented information, while addressing requirements imposed by applicable statutory and regulatory authorities. Documentation is controlled and maintained by the DOO/GM or his designee (Quality Control Manager) and system document control administrators. Quality management system documentation is available to all employees through LD’s system network and PCB electronic information network (TCS document system). Documented quality assurance overview training and specific departmental training is provided, with training records retained, to all new employees at time of hire ensuring awareness of relevant procedures. Customer, statutory and/or regulatory representatives visiting LD are provided access to non-proprietary quality management system documentation.

**Level III – Work Instructions -** Departmental work instructions containing procedures, flow charts, instructions and/or user guides are controlled and maintained by Managers, Supervisors, and the Document Control administrator. These instructions provide operational procedures, forms, work instructions and user guides pertaining to each department’s quality system activities. Each Department is also responsible for identification, preparation, implementation, control and maintenance of retained documented information (See D0001.1017, Document Control System and D0001.1021, Document Change Order). The instructions provide the fundamental directives that ensure accurate and consistent task performance. This level of documentation is made directly available to all employees. Employees receive periodic training to maintain required competencies. All currently approved document listings may be observed in the LD document control areas on the network and/or in the corporate TCS network document control folders

Documented information shall be considered as any hardcopy document or electronic data that is evidence of product conformity to requirements. This evidence of activities performed demonstrates that product, process, or service requirements have been met.

### 7.5.2 Creating and Updating

When documented information is created or updated, procedure D0001.1017 Document Control System illustrates how the information is identified, described, formatted, media type, and the review and approval for suitability and adequacy. Defined approval methods in this procedure identify the required authorization(s) for the types of documentation within the quality management system.

The Director of Operations (or delegated representatives) is responsible to maintain compliance for the Quality Management System Manual and associated user guides and process maps. For departmental documents (work instructions), Managers/Supervisors are responsible for review of the contents and acceptance of documents for their departments.

Documents are reviewed by affected parties prior to their use (see D0001.1017). Additionally, QMS, policies and procedures, departmental procedures, process maps, user guides and forms are reviewed during internal audits of the associated areas. Changes to documents are reviewed and approved by the same functions that performed the original review and approval, unless specifically designated otherwise. Personnel shall have access to pertinent background information upon which to base their review and approval.

Changes to Level III Work Instructions--Manufacturing Documented Information:

Hand-written changes, or corrections, made to manufacturing documentation (i.e. assembly procedures, routers, BOM’s, drawings, etc.), must comply with the Document Control Policy D0001.1017.

* Temporary changes cannot be used for Intrinsic Safe (ATEX) products and must not affect fit, form or function.
* Permanent process or material changes (BOMs, Routers, Drawings, and Assembly Procedures) shall follow the Engineering Change Order (ECO) process D0001.1022.
* A temporary change in work centers can be authorized by a Production Supervisor or by Engineering as long as the change is ***not*** for Intrinsic Safe (ATEX) products, and does not affect form, fit or function of the part. The change must be marked on the Job Router with the authorized person’s initials and date.
* Standard Router changes shall be made by an engineer, only if the below four conditions are met; otherwise the change requires an Engineering Change Order (ECO) form D0001.1021-1 per Engineering Change Order process D0001.1021:
	+ The change does not impact fit, form, function, durability or performance, and there is engineering rationale to support this,
	+ The change is approved by the Lead Engineer,
	+ The change does not require reworking or scrapping of any delivered, in-process or inventoried material,
	+ The change does not affect Program or ATEX controlled products.
* Prototype units built on Engineering Jobs (R&D) that will not be sold to a customer are exempt from LD’s requirements for record control. In the event a unit built on an engineering job is converted into a saleable item, then all records must be completed prior to product shipment.

Changes to quality management system Level II and III controlled documents**:**

Revision of Level II and III controlled documentation (procedures and forms), including to obsolete and or create a new document, shall comply with D0001.1021. The document change requestor must determine who and what areas are affected by the change and obtain required approvals. The approval authorities obtained shall be recorded by Document Control administrator.

Affected parties, at a minimum, shall be all company personnel identified under either the responsibilities section of the document or identified and/or referenced within the body of the document.

For creating or updating documents maintained in the computerized quality management system, the following shall be conducted:

* + Employee shall “copy” the original document to a working file,
	+ Employee shall keep all changes confined to the working file until changes are complete and approvals obtained,
	+ Document Control shall update the master document in our computerized system once the document is approved and ready for release.

Product certified to ATEX and IEC80079-34:

The Intrinsic Safe Products Manager (ISP Manager) (see D0001.0014) ensures that all equipment documents, drawings, EC Type Examination certificates and final calibration certifications are secure, in good condition, and stored in a way that provides easy access to authorized staff.

* + This manager provides training to all staff to assure that all policies and procedures are followed as they relate to intrinsic safe products.
	+ The ISP Manager is responsible for reviewing compliance of information contained within PCB manufacturing documentation with the requirements of the EC-Type Examination Certificate. Related drawings are not approved or amended unless they are in compliance with the schedule drawings.
	+ It is the responsibility of the ISP Manager to obtain documented Notified Body (issuer of the EC Type Examination certificate) endorsement of an EC Type Examination certificate change prior to implementing the change. The Engineering Change Order (ECO) system is used to control these changes (see procedure D0001.1021). All EC Type examination Schedule drawings are entered into PCB Piezotronics, Inc drawing control system to ensure no changes can be made without required approvals.
	+ The ISP Manager may approve related drawings not listed on the EC Type Examination certificate, that are used for detailed manufacturing instruction, provided that the change does not affect compliance of the equipment described in the EC Type Examination certificate and the Directive.

Retained documented information shall remain legible, readily identifiable and retrievable to efficiently serve the customer, statutory and/or regulatory authorities’ needs, as well as for internal and external auditing purposes. Records (D0001.1126) are stored in a suitable environment to protect and prevent damage or deterioration in such a manner as to prevent loss. In some cases, long-term storage may take place within individual departments. In these cases the records are segregated, labeled and organized to facilitate retrieval.

Documented information supporting the use of approved suppliers is defined and controlled per D0001.1068.

In the event nonconforming product has been supplied to the customer; the information / records listed below must be retained as per D0001.1034 Non-Conformant Materials or Products procedure.

### 7.5.3 Control of Documented Information

**7.5.3.1** Documented information required by our quality management system is controlled in the network R drive (R:/Provo/Quality/Quality Management System or on the PCB network R/TCS network folder, and also the TCS Homepage (as they apply to Larson Davis), to ensure that the documented information is available, and suitable for use, where and when it is needed, and is adequately protected. It is the responsibility of all employees to ensure that documented information to be retained by their department are identified and controlled per D0001.1126 Quality Records. It is the responsibility of all employees to ensure that the records they create are identifiable and that the evidence contained therein is accurate and legible whether a signature, initials or assigned stamp. It is the responsibility of all employees to always print their required system forms directly from the controlled network folder or TCS homepage (no photocopying allowed), this ensures not only the latest revision is utilized, but also that the form is complete with no missing information (e.g. a poor quality photocopy). In the event a TCS system document is printed for training, or a similar task, the printed documentation shall be discarded at completion of the task. All employees shall use their legal name as provided to Human Resources department upon their hiring, or the employee number provided by PCB, or the assigned stamp provided by PCB, when completing documented information providing evidence of product or service conformity. No nick-names, symbols, or other information that is untraceable to human resource employee file data, shall be accepted when completing documented information. For TCS system forms were acceptance, authorization, or approval are indicated by an employee’s signature, these forms also require the employee to legibly-print their name in addition to their signature. The legibly-printed name ensures traceability from the signature back to the employee.

The identification system used for controlling quality management system documentation is D0001.1017 Document Control System. It includes forms, procedures, process maps, flow charts, checklists and other such documents as needed.

**7.5.3.2** Methods for the control of our quality management system documented information are defined. Access, retrieval, use, storage, preservation of legibility, control of changes, retention, disposition and the prevention of the unintended use of retained obsolete documented information are defined in procedures: D0001.1017 Document Control; D0001.1126 Quality Records; PCB QAM 7.5 as they apply to LD.

# 8.0 OPERATIONS

## 8.1 Operational Planning and Control

LD plans, implements and controls quality system processes needed to meet the requirements for the provision of products and services, and implements the actions determined during the planning of these processes by (See D0001.1009 Design Control Procedure):

* Determining the requirements for the product or service.
	+ Personal and product safety
	+ Producibility, inspectability, reliability, availability, maintainability, suitability of parts and materials used, embedded software selection, handling, packaging, preservation, and product or service obsolescence
	+ Recycling or final disposal of the product at the end of its life is provided through product markings (e.g. WEEE waste bin symbol) and product user manual directions suggesting compliance to end-user local municipal disposal requirements.
* Establishing criteria for processes and product or service acceptance.
	+ In accordance with the nature of the product or service and associated requirements, statistical techniques may be used for design review parameters involving key characteristics or other significant features.
* Providing resources to achieve product or service conformity and to meet their on-time delivery.
	+ Criteria for our processes and the acceptance of products and services are established and identified and documented
* Implementing process controls in accordance with the established criteria.
* Determining, maintaining and retaining documented information to the extent necessary for ensuring processes have been carried out as planned.
* Demonstrating product or service conformity to requirements.
* Determining the process, production process and controls needed to manage identified critical or key characteristics.
* Engaging representatives of affected planning and control functions.
* Providing the process and resources supporting use and maintenance of our product or service.
	+ Product specification sheets and outline or installation drawings describing proper installation, operation and maintenance are provided with all delivered products
* Determining products and services to be obtained from external providers.
* Establishing controls required to prevent the delivery of a nonconforming product or service to our customer.

LD has planned and manages product or service provision (project management) in a structured and controlled manner appropriate to our organizational, product, service and the customer’s requirements. This includes scheduled events conducted in a planned sequence to meet requirements at acceptable risk and within resource and schedule constraints. The output of this planning process is suitable for our operation with the control of planned changes, and the review of consequences of unintended changes, allow mitigating actions to be taken as deemed necessary. LD ensures that outsourced processes are controlled.

LD has established, implemented and maintains processes to plan and control the temporary or permanent transfer of work and to ensure the continuing conformity of the work to requirements. These processes ensure that work transfer impacts and risks are managed. (See D0001.1009).

### 8.1.1 Operational Risk Management

LD has planned, implemented, and controls processes for managing operational risks to the achievement of applicable requirements including those appropriate to our organization, products and services. Operational risk management identifies the assignment of responsibility, risk assessment criteria, identification, assessment, and communication of risks throughout operations, identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and the acceptance of risks remaining after implementation of mitigating actions (See D0001.1009).

### 8.1.2 Configuration Management

LD has planned, implemented, and controls a process for configuration management appropriate to our organization, products and services ensuring identification and control of physical and functional attributes throughout the product lifecycle. This process controls product identity and traceability to requirements including implementation of identified changes, and ensures that the documented information is consistent with the actual attributes of the product or service (See D0001.1009 and D0001.1017).

* Configuration identification and traceability is maintained within LD’s Business System Database (BSD) controlling all associated product or service documented information.
* Identified changes are controlled through the Engineering Change Order process D0001.1022.
* Configuration management process documented information is verified to ensure consistency with product or service attributes.
* Verification is conducted by the internal auditing process in accordance with the Internal Audit Schedule.

### 8.1.3 Product Safety

LD has planned, implemented and controls appropriate processes needed to assure product safety during manufacturing and the entire product life cycle. During the design planning of a project, consideration is given to internal or end user safety requirements, identified critical product safety parameters, analysis of any reported product safety events and flow-down of any required communication or training. These safety aspects are included in presentations to management during design reviews and other periodic group management meetings. The LD Management team and Engineering Managers are responsible for ensuring product safety requirements are assessed, and that relevant safety documented information is flowed-down to the internal or external end user.

### 8.1.4 Prevention of Counterfeit Parts

LD has planned, implemented, and controls processes appropriate for our organization and product; for the prevention of counterfeit or suspect counterfeit part use or inclusion into products delivered to our customers. Our process considers verification or testing of supplied electronic component items relevant to our products and services.

Products that require intrinsic safe measures may require unique processes in addition to the ones outlined in the QMS. These processes are detailed in D0001.0014 Quality Addendum for Intrinsic Safe Products.

## 8.2 Requirement for Products and Services

### 8.2.1 Customer Communication

LD ensures effective communication with our customers by providing information related to our products and services, handling enquiries, contracts or orders, including changes, obtaining customer feedback and complaints relating to product or service, handling and controlling customer property, and when relevant the establishing of specific requirements for contingency actions.

* Sales representatives communicate with customers by: Providing product or service information, receiving customer enquiries via mail, email, fax and telephone. Sales representatives review customer requirements for quotes and contracts in accordance with Contract Review procedure (SM1005) and Order Received Process (SM02) providing written quotations per Quotation Procedure (SM1003).
* Sales representatives document incoming telephone customer contract requirements and supporting communication records per Order Received Process (SM02). Customer contracts, orders, customer property handling and control, or change requirements are communicated to LD via email, fax, and telephone.
* Sales representatives review customer requirements for quote and contracts in accordance with Contract Review procedures SM1005, SM02 and SM1003.
* Product and customer information, at the discretion of the salesperson, is included with quotations. Product information is controlled on LD’s Web Page and in the specifications that are produced.
* Customer feedback including customer complaints are addressed per applicable process procedures: Customer Feedback (SM1020), Customer Satisfaction (SM24), PCB QAM 10 Improvement and Customer Complaint Procedure (SM25).

### 8.2.2 Determining the Requirements for Products and Services

When determining the requirements for our products and services offered to our customers, LD ensures that; the requirements for the product or service is defined including any applicable statutory and regulatory requirements or those considered necessary by our organization, claims offered for the product or service are met, special requirements for the product or service are determined and operational risks have been identified.

Sales department and the customer determine statutory, regulatory, LD requirements and any special requirements and/or operational risks for a product and/or service, and ensure that these requirements are defined and that the product or service meets the initial claim provided.

### 8.2.3 Review of the Requirements for Products and Services

**8.2.3.1** LD ensures that proper planning has provided the ability to meet the requirements for products and services to be offered to customers. Prior to LD’s commitment to supply product to a customer, Order Received Process (SM02) and contract review process (SM1005) are performed. This review includes:

* customer requirements
* delivery requirements
* post-delivery activities
* known requirements not stated by the customer but necessary for the specified or intended use
* requirements identified by LD
* applicable statutory and/or regulatory requirements
* and requirements differing from those previously expressed

Evaluation and subsequent approval by Sales, Quality, Engineering and Production authorities ensure that product requirements are defined and the ability to meet the defined requirements has been confirmed prior to order acceptance. In the event some customer requirements cannot be met or only partially met, a mutually acceptable resolution with the customer is obtained. Any order requirements differing from those previously defined and agreed upon shall be resolved. When the customer does not provide a documented order or contract, the requirements are confirmed by the sales employee with the customer prior to accepting the order. Other processes that may be used for customer order review are: Export Control and Licensing (SM03) and Specialty Accounts (SM04).

**8.2.3.2** Documented information is retained on the results of review and on any new requirements for product and/or service (see SM1005).

### 8.2.4 Changes to Requirements for Products and Services

Where product requirements are changed, LD ensures relevant documentation is amended and relevant personnel are informed of the changed or revised requirements via one or more of the following applicable processes defined as: Engineering Change Order (D0001.1021) or Amending a Contract (SM1015).

**Note:** For intrinsically safe product, the customer requirements are reviewed for compatibility with the EC Type Examination Certificate (See SM1005 and D0001.0014).

Customer feedback (complaints, concerns or suggestions) is documented through the SM25 and SM012 Quality Concern form or the Corrective--Preventive Action Process, D0001.1020.

## 8.3 Design and Development of Products and Services

### 8.3.1 General

Product development is a planned process that is controlled to the extent of ensuring that the specified requirements are met but that creativity in how they are met is not stifled. The design framework is contained in the Design Control procedure, D0001.1009.

### 8.3.2 Design and Development Planning

The design and development process defines controls that consider:

* Design and development stages
* The nature, duration, and complexity of our design and development activities
* Appropriate review, validation and verification activities for each stage of development
* Responsibilities and authorities for design and development
* Internal and external resource needs
* Functional and performance requirements are adequate to the project
* Applicable statutory and regulatory requirements
* The control of interfaces between persons involved in the design and development process
* Involvement of the customer or end user
* Requirements for provision of the product or service
* Dependent upon complexity, the design plan may be structured into distinct activities whereby each activity defines the required tasks, resources, responsibilities, design content, inputs and outputs, and the ability to provide, verify, test and maintain our products and services

### 8.3.3 Design and Development Inputs

Requirements essential for our types of products and services to be designed and developed consider:

* Functional and performance requirements
* Lessons learned from previous similar design and development activities
* Statutory and regulatory requirements
* Standards and practices that our organization has committed to implement
* Potential consequences of failure due to the nature of the product or service
* Applicable potential consequences of obsolescence

The Project Engineer(s) have the final determination of whether the design inputs are adequate and complete. The Project Engineer in cooperation with the Sales Department and Engineering management is responsible for resolving ambiguous or conflicting information and updating the appropriate documented information for the project.

Changes required after the product is finalized and released are reviewed, validated, verified and approved by Engineering through the Engineering Change Order procedure, D0001.1022 prior to implementation.

### 8.3.4 Design and Development Controls

Controls applied to our design and development process ensure:

* That the results to be achieved are defined
* Periodic reviews are conducted to evaluate our ability to meet design and development requirements
* Verification activities are conducted to ensure design and development outputs meet the input requirements
* Validation activities are conducted to ensure our resulting product or service meets the requirements for the specified application or intended use
* Necessary actions are taken on problems detected during review
* Retained documented information of these activities
* Authorization for progression to the next design plan stage
* Representatives of functions concerned with the design and development stage being reviewed are included

**8.3.4.1** Tests necessary for verification and validation activities are planned, controlled, reviewed, and documented to ensure and provide evidence:

* That test plans or specifications identify the test item and the required resources
* Test objectives and conditions are defined
* Parameters to be recorded and the relevant acceptance criteria
* Test procedures identify test method to be used and how to perform and record test results
* Confirming that correct configuration of the test item is used for testing
* The test plan and test procedure requirements are observed and acceptance criteria are met
* Monitoring and measuring devices used for testing are controlled per requirements of the ISO17025 standards

At completion of our design and development process, test reports, calculations and test results are retained as documented information demonstrating that the design for the product or service meets the specification requirements for all operational conditions. (See D0001.1009).

### 8.3.5 Design and Development Outputs

Our design and development process ensures: (See D0001.1009 for more details)

* Design outputs / product realization meet design and development criteria
* Appropriate monitoring, measuring and acceptance criteria is defined
* Product or service characteristics that are essential for their intended purpose and their safe and proper provision are realized
* Any applicable critical or key characteristic and specific actions required for these items are defined
* All outputs are approved by authorized personnel prior to release
* Data required to allow the product to be identified, manufactured, verified, used and maintained is defined
* Processes and procedures for production and service of the product have been provided and accepted
* Product acceptance criteria have been met and approved by regulatory agencies where applicable
* Manuals, datasheets and product specification have been published detailing essential functions, safe and proper use where applicable
* Design and development reviews are held regularly to validate design requirements and document changes
* The level of records and documentation needed for verification of product requirements and validation of design goals and criteria including regulatory requirements

### 8.3.6 Design and Development Changes

Design changes to our products or services are identified, reviewed and controlled either during or subsequent to the design and development process ensuring there is no adverse impact on conformity to requirements. Our design and development process defines criteria for customer notification, prior to implementation of changes that may affect their requirements. Documented information is retained for design and development changes, results of design reviews, authorization of design changes and the actions taken to prevent adverse impacts. (See D0001.1009 and or D0001.1021)

## 8.4 Control of Externally Provided Process, Products and Services

###  8.4.1 General

LD maintains documented procedures to ensure that externally provided processes, products, and services conform to specified requirements; see D0001.1068 and PCB QAM 8.4 as it applies to LD processes. LD maintains responsibility for the conformity of all externally provided processes, products, and services including those sources defined by our customers. When designated by our customers, approved external providers and sources, including special processes, are used. Risks associated with the use of such external processes, products, or services, as well as the selection and use of these external providers, are identified and managed. Appropriate controls are applied to external providers and require that these providers flow-down appropriate controls to their direct and sub-tier external providers to ensure that requirements are met. Controls to be applied to externally provided processes, products, and services are determined:

* when the externally provided product or service is intended for incorporation into our own products and services;
* are provided directly to the customer by the external provider on behalf of our organization;
* when a process, or part of a process, is provided by an external provider as a business decision of our organization;

Criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers has been determined and applied based upon their ability to provide processes or products and services to requirements. Documented information of these activities is retained including any necessary actions arising from these evaluations.

### 8.4.2 Type and Extent of Control

Documented quality system processes ensure that externally provided processes, products, and services do not adversely affect our ability to consistently deliver conforming products and services to our customers. Externally provided processes are subject to the controls required by our quality management system that define both the controls applicable to the external provider and their resulting output. Consideration is given to the potential impact of the externally provided process, product, or service upon our ability to consistently meet customer and applicable statutory and regulatory requirements. Effectiveness of controls applied to the external provider and the results of periodic external provider performance reviews, as well as necessary verification activities, ensure that the externally provided process, product or service meets requirements.

Verification activities for externally provided processes, products, and services are performed in accordance to the risks identified by our organization. These activities include applicable inspection or periodic testing when there is high risk of nonconformities including counterfeit parts. Our organization is responsible for provisioning acceptable processes, products, and services that comply with requirements regardless of any other interested party verification activities. Verification activities for our external providers include, but are not limited to:

* Review of requested certifications for material
* Process, product, or service, test reports, manufacturing records
* On-site quality system assessment
* Inspection of products or verification of service upon receipt
* Review of any delegations to the external provider

LD does not release any externally provided product for production use until all required verification activities have been completed. In the event our organization delegates verification activities to an external provider, the scope and delegation requirements will be defined and a register of delegations maintained. Delegated verification activities will be periodically monitored to ensure continued effectiveness.

###  8.4.3 Information for External Providers

Purchase order requirements are reviewed for adequacy prior to communication to the external provider. This communication ensures that our external providers possess the requirements for the process, product, or service being provided including identification of relevant technical data. LD also communicates to external parties our requirements for the approval of products, services, methods, processes, equipment and the release of products and services. Communication to external providers also defines their need to implement a quality management system, use customer-designated or approved external providers including those performing special processes, notifying our organization of any nonconforming process, product, or service and obtaining an authorized approval for disposition, preventing the use of counterfeit parts, notifying our organization and obtaining prior approval for any changes to processes, product, or service. LD, our customers, and regulatory authorities require right of access to all applicable areas of facilities and documented information, at any level of the supply chain. This activity ensures that affected persons are aware of their contribution to the conformity of products and services, product safety and the importance of ethical behavior.

Intrinsic Safe products certified to ATEX and IEC80079-34 are controlled by D0001.0014 Addendum for Intrinsic Safe Products. LD purchase order documents will clearly describe the specific requirements pertaining to subcontracted product documented in the EC type-examination certificate and equipment documents (e.g. for process control, testing or inspection). The Intrinsic Safe Manager and buyer are responsible for reviewing and ensuring these requirements are defined in the purchase order.

For product where conformance cannot be verified after manufacture (e.g. encapsulated intrinsically safe circuits) the purchasing information will describe the specific quality procedures, resources and sequence of activities relevant to the particular item ordered. The Intrinsic Safe Manager will provide the purchasing department the required information addressing these requirements with the Purchase Requisition Form.

LD maintains traceability of purchase order documentation to supplied product (and corresponding documentation) through BSD purchase order number.

## 8.5 Production and Service Provision

###  8.5.1 Control of Production and Service Provision

LD has implemented production and service provision under controlled conditions that include, as applicable:

* The availability of documented information defining the characteristics of the products being produced including schematics, bills of materials, etc., as necessary for production or service
* The availability of work instructions where the absence of the documents has the potential to affect quality
* Services to be provided, activities to be performed and the results to be achieved
* Availability and use of suitable monitoring and measuring resources
* Implementation of monitoring and measuring activities at appropriate stages to verify criteria for control of processes or outputs
* Acceptance criteria for products and services
* Monitoring and measuring activities for product acceptance provides documented information that includes the criteria for product acceptance or rejection, where the manufacturing sequence verification operations are performed, measurement results retained as evidence of acceptance or rejection, and required monitoring and measuring equipment with associated instructions for use
* When sampling is used as a means of product acceptance, the sampling plans are based upon recognized statistical principles, standards, or based upon criticality of the product and/or the process capability
* Documented information also defines the use of suitable infrastructure and environment for operating our processes and the appointment of qualified or competent persons
* For special processes whereby the resulting output cannot be verified by subsequent monitoring and measurement, validation and periodic revalidation is conducted to confirm planned results are achieved
* Additional controlled conditions include:
	+ The implementation of actions to prevent human error
	+ Delivery, and post-delivery activities
	+ Established workmanship criteria
	+ Accountability of all products during production
	+ Methods for measuring variable data are defined
	+ The identification of in-process inspection points when adequate verification of conformity cannot be performed at later manufacturing stages
	+ Documented evidence demonstrating that all manufacturing, inspection and verification operations have been completed as planned
	+ Provisions for the prevention, and the control and monitoring of utilities and supplies that may affect conformity to product requirements

### 8.5.1.1 Control of Equipment, Tools, and Software Programs

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes are validated prior to their final release and are maintained. Requirements are defined for the storage of production equipment and tooling including periodic preservation checks.

### 8.5.1.2 Validation and Control of Special Processes

Production and service processes are validated prior to implementation into the production system. The processes are validated as part of the product design or if the process is not tied to a particular product, it is validated during the research phase of the project.

When a process is not validated by production monitoring and measurement then the following will be used to specify the process:

* Defined criteria for review and approval
* Specify measurement and monitoring equipment
* Specify employee qualifications
* Provide procedures and work instructions
* Determine records to retain
* Set specifications for revalidation if there is a change in the process

Variations to the processes are documented through the use of the Product Waiver Form D0001.1023; however, if the change to the process is long-term or permanent then the change is made using the Engineering Change Order procedure, D0001.1022 or the Document Change Order procedure, D0001.1021.

### 8.5.1.3 Production Process Verification

LD has implemented production process verification activities to ensure our production processes are able to produce products that meet requirements. Part of the design release process requires that an ME Build (Manufacturing/Engineering) be completed and monitored by the project engineers. This build is used to verify that the production processes, production documentation, and tooling are able to provide parts and assemblies that meet requirements. Changes resulting from this build are recorded and made prior to the release of the product.

### 8.5.2 Identification and Traceability

LD uses suitable means for identifying outputs when it is necessary to ensure conformity of our products and services. Products manufactured and services provided by LD are tracked through the manufacturing process by job order number. Where appropriate, the finished products are tracked by serial and model number. Where output traceability is required by regulatory requirements i.e. Intrinsic Safe products (ATEX), LD will track and maintain records of the production process for the designated time period. The process used for providing identification and traceability is the Product Identification & Traceability procedure, D0001.1028.

### 8.5.3 Property Belonging to Customers or External Providers

LD exercises care when handling or using customer or external provider property while under our control. The property provided for use or incorporation into our products and services is product, materials, software, personal data and/or intellectual property. It is identified, verified, protected, and safeguarded. In the event such property is lost, damaged, or otherwise found to be unsuitable for use, documented information on what has occurred is retained and reported to the customer or external provider. (See D0001.1058, Control of Customer Supplied Product procedure.)

### 8.5.4 Preservation

LD preserves conformity during internal processing and delivery to the intended destination. Preservation includes identification, handling, contamination control, packaging, storage, transportation and protection. Preservation applies to finished goods, inventory or items supplied to Larson Davis by a customer for repair and/or calibration. When required by specification or in accordance with statutory or regulatory requirements preservation of output includes:

* Cleaning
* Detection—Identification
* Handling
* Packaging
* Storage
* Marking and labeling—including safety warnings and cautions
* Shelf life control and stock rotation
* Special handling and storage for hazardous materials
* Protection of products and customer supplied product

Items that are inventory are received and verified per the Purchasing procedure, D0001.1068. Inventory items receive an in-house identification number and are stored by that number. Internal part numbers are assigned per the Item Creation procedure, D0001.1024.

Finished goods are stored by model prior to shipment to the customer.

Product returned from a customer is received per the PCB Return Material Authorization (RMA) procedure, SM1009. The products are then delivered to the Service and Repair Department for processing or as indicated by Sales via contract, email, verbal or other communication.

Finished goods, inventory or supplied items are protected from damage while in the possession of LD through handling and packaging appropriate for the item. The procedures for protection include but are not limited to:

* Packaging & Handling, D0001.6070
* Shipping, D0001.1044
* ESD, D0001.1102

### 8.5.5 Post-Delivery Activities

LD ensures post-delivery activities associated with our products and services meet their requirements. The extent of post-delivery activities required considers statutory and regulatory requirements, potential undesired consequences associated with the product or service, the nature, use, and intended lifetime ofthe product or service, customer requirements and feedback, collection and analysis of in-service data, the control, updating, and provision of technical documentation related to product use, maintenance, repair, controls for any work undertaken outside our facility, and customer support. In the event problems are detected after delivery, appropriate investigative and reporting action is taken. Post-delivery activities can also include warranty provision, recycling, and final disposal instructions. (See SM012 Quality Concern).

### 8.5.6 Control of Changes

LDreviews and controls changes for production and service provision to the extent necessary for ensuring conformity with requirements. Persons authorized to approve production or service provision are identified. These changes can include those affecting processes, production equipment, tools or software programs. Documented information describing the results of the review of changes, persons authorizing the change, and any necessary actions arising from the review are retained. (See D0001.1020, D0001.1021, D0001.1022 and D0001.1023 procedures)

## 8.6 Release of Products and Services

LD has implemented planned inspection processes and arrangements at appropriate stages to verify our product or service meets requirements. Products and services are not released to the customer until the planned arrangements have been completed or unless authorized by a relevant authority and, as applicable, by the customer. See D0001.1009 Design Control and D0001.1023 Waiver Procedure.

Purchased products and services are routed to Quality Assurance for inspection to purchase order requirements when indicated in BSD QCS supplier module, or as directed by the Quality Assurance Manager. Inspection requirements are entered as notification into the BSD QCS supplier software accessed by the receiving department

Documented information is retained on the release of products and services including evidence of conformity with the acceptance criteria, and traceability to the person(s) authorizing the release. To demonstrate product qualification, documented information is retained providing evidence that the product or service meets requirements. Documented information required to accompany the product or service is provided at delivery.

## 8.7 Control of Nonconforming Outputs

**8.7.1** Outputs that do not conform to their requirements are identified and controlled to prevent unintended use or delivery. Nonconforming outputs include nonconforming product or service generated internally, received from an external provider, or identified by a customer. Appropriate action is taken based upon the nature of the nonconformity and its effect on conformity of our products and services. (See D0001.1034 Non-Conformant Materials)

This activity also applies to nonconforming products and services detected after the delivery of products or during or after the provision of services. Our nonconformity control process is maintained as documented information including provisions for:

* defining responsibility and authority for review and disposition of nonconforming outputs
* the process for approving persons making these decisions
* taking necessary action to contain the effect of the nonconformity on other processes, products, or services
* reporting in a timely manner nonconformities affecting delivered products and services to our customers and relevant interested parties (e.g., external providers, customers)
* defining corrective actions for nonconforming products and services detected after delivery as appropriate to their impact

Nonconforming outputs are addressed by correction activities, segregation, containment, return or suspension of the product or service, customer notification, and obtaining authorization for acceptance under concession by a relevant authority and when required by the customer.

Nonconforming product dispositions of use-as-is, or repair, are only implemented after obtaining approval from an authorized representative responsible for the design (or person having delegated authority from our design department), or after documented authorization is provided by our customer; in the event the nonconformity results in a departure from the contract agreement.

Product dispositioned for scrap is conspicuously and permanently marked and/or positively controlled until physically rendered unusable. Counterfeit, or suspect counterfeit parts are controlled to prevent reentry into the supply chain. When nonconforming outputs are corrected, verification to requirements is conducted demonstrating conformity.

**8.7.2** Nonconforming output documented information is retained that describes the nonconformity, actions taken, any concessions obtained, and the identification of relevant authorities making the decisions (See NCN reports D0001.1034-1).

# 9.0 PERFORMANCE EVALUATION

## 9.1 Monitoring, Measurement, Analysis and Evaluation

### 9.1.1 General

LD has implemented policy metrics for monitoring, measuring, analysis, evaluation and process improvement needed for demonstrating: conformity of product, conformity of the quality management system, and to continually improve the effectiveness of the quality management system. The policy metrics support our quality objectives defined in our Quality Management System Manual. Analyzing and evaluating the results of monitoring and measurement is performed during management review meetings. The quality management system has developed identifying processes with assigned metrics for tracking effectiveness. The metrics described in these processes are documented and reported to management at their prescribed intervals through policy metrics monitoring. The Management Team conducts quality system reviews whereby all identified process metrics are reviewed. Policy metrics documented information is retained as evidence of compliance.

### 9.1.2 Customer Satisfaction

Larson Davis monitors customers’ perception of the degree to which their needs and expectations are being fulfilled. The methods for obtaining, monitoring and reviewing this information are defined per Customer Satisfaction (SM24). The information is obtained through customer-initiated contact or Sales initiated contact and may be documented (depending on the nature of the contact) via a Quality Concern form (SM012), Contract Review (SM1005), Quotation (SM1003) or the Customer Satisfaction Feedback procedure (SM1020). The Sales department reports on these measures to management.

Product certified to ATEX (IEC80079-34)is handled in the same manner as other manufactured products. This is due to the fact that all product returns and/or complaints are addressed through our internal corrective action system whereby subsequent root cause investigation promotes review of product compliance to specifications during failure analysis and/or other technical review(s). See D0001.0014 Quality Addendum for Intrinsic Safe Products for additional information.

Policy metrics information monitored and used for the evaluation of customer satisfaction includes, but is not limited to, the quality objectives for product and service conformity (Quality At The Customer), On-Time Delivery, Scrap As Percent Of Sales, Shipments As Percent Of Goal, and customer complaints and corrective action. Deficiencies identified by these evaluations are assessed for the effectiveness of customer satisfaction process improvement.

### 9.1.3 Analysis and Evaluation

The Management Team and department managers and/or supervisors analyze and evaluate appropriate monitoring and measurement data in management reviews. Appropriate data may also include information on product and service problems reported by external sources such as industry alerts and advisories. The results of this analysis are used to evaluate:

1. conformity of products and services
2. the degree of customer satisfaction
3. the performance and effectiveness of the quality management system
4. if planning has been implemented effectively
5. the effectiveness of actions taken to address risks and opportunities
6. the performance of external providers
7. the need for improvements to the quality management system

Where applicable, the Design Control Procedure D0001.1009 reviews the critical elements within individual products and/or processes. Implementation of statistical analyses of these characteristics provides improved process control and measurement of process capability (see D0001.1168). Measurement of key performance measures is performed by Quality Assurance Inspection personnel and/or appointed applicable delegates in the production department and quality assurance receiving inspection procedures. Actions based upon the review and evaluation of critical inspection measurement results enhances product and process conformity, contributing to the overall continuous improvement process.

Intrinsic Safe Products: Product certified to ATEX (IEC80079-34) and any relatedprocess that may affect the integrity of protection, where the resulting integrity cannot be verified after manufacture, are identified by the Intrinsic Safe Products Manager responsible for documenting monitoring and measurement criteria suitable for providing evidence of product conformity (see D0001.0014).

## 9.2 Internal Audit

LD conducts ongoing audits of the QMS per the Internal Audit procedure, D0001.1166 to ensure that the QMS conforms to international standards and that quality objectives established by management are being effectively implemented and maintained.

**9.2.1** Internal audits are conducted per the audit schedule at planned intervals taking into consideration the status and importance of the processes and areas to be audited, the status of previous audits and specially assigned supplemental audits requested by management. The auditor is responsible for completing the audit (closing meeting held per the requirements of this procedure) in accordance with the audit schedule.

The audit schedule addresses, at a minimum, the ISO-9001, ISO-17025 and IEC80079-34 standards and all other applicable system standards, Quality Management Systems, customer and applicable statutory and regulatory quality system requirements, as well as follow-up verifications assessing the effectiveness of corrective and preventive actions resulting from previous internal or external audit findings. This planned schedule ensures effectively implemented and maintained compliance of all areas to the applicable standard requirements of the quality management system. The management review process evaluates audit results to confirm the status of the implemented and maintained QMS.

**9.2.2** The audit criteria, scope, and frequency are defined by the Quality Assurance Manager or his designee and documented on the planned audit schedule as necessary to meet LD, Registrar, Customer Contract and/or Regulatory requirements (see D0001.1166). The Quality Assurance Manager ensures all applicable standards clauses/elements are audited at a minimum of once a year. The Quality Assurance Manager identifies the extent of the audit and areas to be audited and weighs the additional importance of certain clauses based on Internal Auditor suggestion and management input. The Quality Assurance Manager may update the audit schedule at any time for the addition of a supplemental process audit or a limited scope audit commensurate with status, importance and current activities within the quality management system.

Selection of auditor(s) and conduct of audits ensure objectivity and impartiality of the audit process. Auditors do not audit their own work. The Internal Auditor List (D0001.1166-4) is maintained, reviewed and/or revised by the Quality Manager. The Internal Auditor List indicates what training qualifies each auditor. Training may include: ISO9001, ISO17025, IEC80079-34 and any other applicable system standards. Also included is an overview of Quality Management System, specifically section 9.2 Internal Audit. Auditor(s) must perform a minimum of one internal audit per year to maintain qualification status. Auditor effectiveness and information accuracy is reviewed by the Quality Assurance Manager following the audit’s closing meeting, at time of report review, as evidenced by signature on Audit Report QA004.

Verification activities shall include the actions taken and the reporting of the verification results as detailed in D0001.1166.

Product certified to Intrinsic Safe Standards—ATEX and IEC80079-34. When the Audit Schedule is reviewed for the coming year, a vertical audit shall be included whereby a product awaiting dispatch is used to prove all aspects of the system associated with the production of that product from a certification viewpoint. The sample of models selected should not be the same as previous year’s audit if another product is available. The audit must include: documentation (drawings, inspection records/checklists, test records, material certifications, etc.) product identification, handling, storage, training and any other recognized variable that can affect compliance of the product to the Type Examination Certificate documentation parameters (see IEC80079-34 standard and D0001.0014).

## 9.3 Management Review

### 9.3.1 General

The LD Management team reviews the QMS periodically (usually quarterly but not less than annually) per the process described in the Management Review procedure, D0001.1164. The primary purpose is to ensure continued suitability, adequacy, effectiveness, and alignment of the quality management system processes with our strategic direction. The quality policy, mission statement and policy metrics (quality objectives) are reviewed and evaluated to identify any opportunities for improvement and determine if any revisions are warranted. Actions resulting from Management Review meetings are recorded on form D0001.1164-2 or QA139. The Inputs and outputs of this review are documented as part of the minutes using the Management Review Minutes Form, D0001.1164-2.

###  9.3.2 Management Review Inputs

Management reviews are planned and conducted periodically using the Management Review Meeting Minutes template (D0001.1164-2 or QA139). This template addresses the following input parameters as required by ISO 9001, ISO17025 and IEC80079-34 quality management system requirements:

1. the status of action items from previous management reviews
2. changes in external and internal issues relevant to our quality management system
3. information on the performance and effectiveness of our quality management system including trends for:
	1. customer satisfaction and feedback from relevant interested parties
	2. the extent to which our quality objectives have been met
	3. process performance and conformity of products and services
	4. nonconformities and corrective actions
	5. monitoring and measuring results
	6. internal and external audit result
	7. the performance of external providers
	8. on-time delivery performance
4. the adequacy of resources
5. the effectiveness of actions taken to address risks and opportunities
6. opportunities for continual improvement
7. review of Intrinsic Safe (IEC80079-34) product program effectiveness
8. calibration services and certifications; including status of our quality standards
9. workplace safety
10. reaffirm accuracy of training, document control, internal auditors and training, material review boards, and corrective actions taken

###  9.3.3 Management Review Outputs

 The output from the management review includes decisions and actions related to:

* Improvement of the effectiveness of the quality management system, its processes and risks.
* Improvement of the product related to customer requirements.
* Resource needs.
* Recommended changes to quality objectives.
* Recommendations for corrective--preventive actions.
* Suggestions for continuous improvement.
* Quality System improvements as related to Intrinsic Safe products.

When the function and implementation of the overall Quality Management System (QMS) is acceptable to the LD Management team then it is documented in the minutes that the QMS is to continue in effect until the next management review.

# 10.0 IMPROVEMENT

## 10.1 General Guidelines

LD continually works to improve the effectiveness of the QMS through the implementation of the quality system, internal and external audit results, analysis of data, corrective--preventive action, risk assessment and management reviews. These actions are taken to meet customer requirements and enhance customer satisfaction. Actions taken may include:

* Improving products and services to meet requirements as well as to address future needs and expectations.
* Correcting, preventing or reducing undesired operational outcomes and effects.
* Improving the performance and effectiveness of our quality management system.

Documented information, as defined in this section, is retained as evidence of the nature of the nonconformities and any subsequent actions taken, and the results of any corrective action. Significant implemented corrective action is reviewed and verified at a later date to ensure additional nonconformities have not occurred and that the solution is effective. Records of implemented corrective and preventive action with their corresponding results are maintained in the format(s) described in this section. Additional requirements are also documented in D0001.1020 and PCB QAM 10.0.

1. Corrective Action Requests (CAR) follow the actions detailed in SM25—Customer Complaint Process. These include customer complaints or a product within its warranty period and substantiated as being the fault of LD by subsequent failure analysis. For Failure Analysis a Return Material Authorization (RMA) per SM09 is issued for tracking and control of the customer supplied product. Returned products are processed in Repairs Department. A CAR entry may be generated in the event of a situation in which a typical customer would complain. To initiate a corrective action request follow SM25.
2. For returns that, through failure analysis have been determined to be damaged by customer misuse (e.g.: the customer over-powered or over-shocked the unit), the customer will be notified of the analysis by the sales representative (CSR) performing the feedback procedure. The CSR will inform the customer of the failure analysis result, explain how the problem occurs and advise how to avoid future occurrence.
3. For internal suppliers, a Material Disposition Report (MDR QA020) is completed and entered into the MDR database when material from an internal supplier is nonconforming. If containment is necessary follow containment process. The MDR shall be submitted to the Quality department for processing and entry into the MDR database.
4. For an externally provided product, a NCN report is completed and processed according as outlined in D0001.1034 and on form D0001.1034-1. A supplier corrective action may be initiated depending on the severity and frequency of the nonconformance. Responses from suppliers deemed ineffective may prompt performance review, notification and potential removal from register of approved suppliers (see D0001.1068).
5. For a LD delivered process, product or service, a Corrective Action Request (CAR) should be initiated (SM25), in a timely manner, by any employee who becomes aware of the nonconforming product or service, unless the employee has specific knowledge that this defect has already been reported in a previous entry. This action ensures that immediate evaluation of containment action is taken.
6. Containment activities resulting from a customer complaint, CAR, MDR or NCN are defined in the specific procedure pertaining to the action.
7. All returned explosive atmospheres (ATEX) product will be reviewed by the service department (see SM1009 RMA procedure). Upon receipt of product and failure review, the following action will be taken:
	1. If it is determined that the failure was not the fault of LD, or that further investigation into the incident would likely not produce any process improvement or problem reduction, a corrective action need not be initiated. Such situations might include, but are not limited to:
		1. The existence of clear evidence of customer misuse or negligence,
		2. An analysis that cannot conclusively identify a Root Cause of failure,
		3. A failure mode that is currently known and being addressed.
	2. If it is determined that the failure may be the fault of LD, the Intrinsic Safe Manager will be involved in all corrective actions.
8. The corrective action assignee is responsible for obtaining, documenting and completing the required information by the indicated due date for timely closure.
9. Corrective action (CA) requiring follow-up verification, as indicated by quality assurance management on either the document or database entry, are evaluated to ensure effective functioning of the internal corrective action system. All customer notification or recall CA’s shall be selected for follow-up verification. The quality department identifies the CA’s due for verification including the designated assignees. Verification of CA effectiveness may be based upon severity of issue, presence of any recurrent workmanship deficiency, need for continuous improvement plan evaluation, or to assure comprehensive coverage of all manufacturing center processes, products or services. All verifications are distributed for completion monthly.
10. In the event a product recall or customer notification is realized, a Corrective Action Request (CAR) must be issued for proper tracking and return of affected product or customer notification. The affected product models with total quantity(s), corresponding serial numbers if assigned, list of customers and/or distributors, and copy of customer notification letter, at a minimum, shall be documented in the Material Review Board minutes. The Management Team is responsible for ensuring timely and effective reporting, of a recall or notification, to Quality Assurance Management in the form of a completed and approved corrective action document and to the legal department.

## 10.2 Nonconformity and Corrective Action

Nonconformity actions and corrective actions are the reactions or fix to a problem that has occurred. LD works to eliminate the root causes of non-conformities in order to prevent recurrence. Action is taken in proportion to the impact of the problem.

When nonconformity occurs, including any arising from complaints, employees are responsible for complying with our quality management system processes in the effort to:

* react to the nonconformity and, as applicable, take action to control and correct it and deal with the consequences,
* evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere by:
	+ Reviewing and analyzing the nonconformity
	+ Determining the causes of the nonconformity, including non-conformities related to human factors (commonly referred to as “human error”, this response is not acceptable. The lower-level specific root cause shall always be used when determining corrective action to be taken). Use of the Five Whys methodology to determine the root cause
	+ determining if similar non-conformities exist or could potentially occur
* implement any action taken
* review the effectiveness of any corrective action taken
* update any necessary risks and/or opportunities determined during planning
* making any necessary changes to the quality management system
* flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity
* take specific actions when timely and effective corrective action is not achieved

Risk review is a preventive action and may include:

* Action plans to prevent the occurrence of non-conforming product or processes.
* Non-conformities and corrective action plans that prevents a re-occurrence of the initial problem or foreseen problem.
* Plans and actions that may result from risk assessment.

The actions taken are proportional to the impact of a possible future nonconformity.

Larson Davis empowers its employees to seek resolution of potential non-conformities through informal processes. This methodology allows rapid action with minimal impact on employee resources; it also encourages cross-departmental communication and therefore a more pleasant and efficient work environment. Employees are encouraged to document requested actions that require coordination of multiple departments or the scheduling of another employee’s time.

The procedures governing this process include the LD D0001.1020 Corrective Action Process and PCB QAM 10.0 as they relate to tracking, documenting and following these processes from a corporate level. These procedures also document that actions taken for resolution of the concerns and the methods used for follow-up review of the effectiveness of the actions taken in the nonconformity and corrective process.

Corrective action taken shall be appropriate to the effects of the nonconformity encountered. Documented information is maintained that defines the actions taken (see SM012).

## 10.3 Continual Improvement

LD continually improves the suitability, adequacy, and effectiveness of the quality management system considering the results of analysis and evaluation, and also management review outputs, to determine if there are needs or opportunities that should be addressed as part of continual improvement. Implementation of improvement activities are monitored and evaluated for the effectiveness of their results. Continual improvement is also achieved through best design practices (see procedure D0001.1020).

Some methods utilized to continually improve our quality management system are:

1. The Internal Audit System (D0001.1166) providing maintenance of the quality management system documentation.
2. Performance data (on-time delivery, customer feedback, etc.) is posted in departments providing a gauge for all employees. The data is reviewed in departmental daily meetings, staff meetings, monthly company meetings and other meetings hosted by the senior leadership team and company president.
3. Core competency and job training programs as per D0001.1005
4. Lean Manufacturing and Six Sigma Programs as they apply to our processes
5. Corrective action(s) evaluation and actions taken,
6. Customer Service Feedback and survey information trends - Total Customer Satisfaction (SM24).

The design stage for new products and services (See D0001.1009) may involve methods such as Design for Manufacturing (DFMA), Design Failure Mode and Effects Analysis (DFMEA) and/or Process Failure Mode and Effects Analysis (PFMEA); in the event that current documented best design practices and associated risk information is considered insufficient. Risk priorities and customer requests are reviewed during management reviews and monthly departmental reviews to determine where corrective action is required for reducing risks to an acceptable level. Engineering management confirms effective preventive actions are employed during departmental project review meetings.

# 11.0 REVISION HISTORY

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **DCO #** | **REV** | **DATE** | **INITIALS** | **CHANGES MADE** |
|  | A | 1991 | JEB | Initial Quality Manual |
|  | B | 1994 | JEB | Revised Quality Manual to include Service, Training and Organization information |
|  | C | 7/99 | JEB | Total re-write of the Quality System to document current practices and process based management. |
| 592 | D | 6/30/03 | JEB | Rewrite of the QMS to include the concepts of ISO 9001-2000 and to include new procedures and corporate structure. |
| 633 | E | 9/19/03 | JEB | Edited the quality processes and created a different type of flow chart to address auditor concerns. Edited, tweaked and added information to address auditor concerns from pre-assessment. |
| 775 | F | 3/30/04 | JEB | Larson Davis verifies its processes and products and is therefore excluded from the requirements of ISO 9000-2001 section 7.5.2. (per audit results) |
| 971 | G | 6/21/06 | JEB | Incorporated ATEX requirements, updated section on company organization and improved grammar/punctuation. |
| 1023 | H | 6/26/07 | JEB | Added ISO 7.5.2 reference to section 5.4.1 to correct an audit nonconformity. Updated to include PCB procedural references as appropriate and to change company references to reflect PCB divisional status. |
| 1108 | I | 5/23/08 | DAR | Updated to ISO9001-2008 changes |
| 1211 | J |  | DAR | ISO9001-2008 updates and clarifications |
| 1278 | K | 4/7/10 | DAR | General updates split out commitment on intrinsic safe products. |
| 1409 | L | 9/17/12 | DAR | General updates |
| 1413 | M | 12/17/12 | HSA | Replaced old Standard number with new Standard number |
| 1467 | N | 10/24/13 | SJA | Added section 2.8 to meet A2LA ISO 17025 requirements |
| 1490 | O | 4/25/14 | SJA | Added mention of Accreditation Body in section 2.8 and reference to D0002.0005 |
| 1507 | P | 7/24/14 | DAR | Updates to Quality Policy to bring in line with corporate changes. |
| 1603 | Q | 1/29/16 | ADB | Update to Quality Process Table to clarify intrinsic safe products meet Ex Certificate requirements |
| 1761 | R | 11/13/17 | DAR | Updates for ISO9001-2015 |
| 1805 | S | 2/20/18 | DAR | Change Management Review and match more closely the QAM recently updated by PCB |

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