

LARSON PACKAGING COMPANY Quality Manual LPC-MAN-1000 Revision 5 – January 23, 2023



Quality and Business Management System (Quality Manual)

Conforms to ISO 9001:2015



Revision 5-Issued January 23, 2023



Distribution and Control

This is an updated quality manual for requirements specified in ISO 9001:2015 Standards. This version replaces all prior issues. But more than a "quality manual," it describes and documents Larson Packaging Company's Business Management System and relays to customers how we do things.

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Using this Quality Manual

This quality manual provides an overview of Larson Packaging Company Milpitas' policies and procedures for various activities. A copy of this quality manual is available for review by our customers, suppliers, employees, potential customers, third party auditors, and regulatory agencies, if applicable.

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1.0 Welcome to Larson Packaging Company (LPC)



Larson Packaging Company designs and manufactures custom shock and vibration protective packaging for high tech and industrial companies in the Silicon Valley and in San Diego.

This comprises products such as crates, ATA cases, molded plastic cases, pallets, and foam cushioning systems, that protects products/capital equipment during transit. The packaging is customized to optimize a set of customer requirements that might include multiple use, testing, ease of use, monitoring, presentation, and fulfillment. Our manufacturing can be very precise where required. Our objective is to perform all duties related to these functions in an effective, efficient and reliable manner using documented procedures and standards that are regularly reviewed. Our principal goal is to deliver a repeatable, quality product on-time, every time to meet customers' schedules.

To support its belief in the excellence of what we do we have developed and implemented a quality management system based on the Standard ISO 9001:2015. This provides both quality assurance for the customer and cost-effective quality management for the Company.

The Quality System described in this Manual and the corresponding Quality Procedures cover the manufacturing, repair and distribution of custom industrial packaging products to customers of all sizes and types.



2.0 About the LPC Quality Manual

This manual is prepared for the purpose of defining the company's interpretations of the ISO 9001:2015 international standard, as well as to demonstrate how the company complies with that standard.

This manual presents "Notes" which are used to define how LPC has tailored its management system to suit its purposes. These are intended to clarify implementation approaches and interpretations for concepts which are not otherwise clearly defined in ISO 9001:2015. *Notes appear in italics, with gray background.*

Where subordinate or supporting documentation is referenced in this manual, these are indicated by **bold italics**.

Why us





Fast turnaround







3.0 Terms, Definitions, and Applicable Industry Standards

LPC adopts the following terms and definitions within its Quality Management System. Where no definition is provided, the company typically adopts the definitions provided in *ISO 9000: Quality Management – Fundamentals and Vocabulary*. In some cases, specific procedures or documentation may provide a different definition to be used in the context of that document; in such cases, the definition will supersede those provided for in this Quality Manual or ISO 9000.

General Terminology and Abbreviations

ACTV – Actvcontent manufacturing effectiveness system. Tablet and cloud-based system on the plant floor

BMS - Business Management System

Bucket – A quantity of work, usually less than 20 estimated total man hours. Multiple buckets may make up an order

CAPA – Corrective and Preventive Action

CAR - Corrective Action Report

CRM – Customer Relationship Management

Cutlist – Document bill of materials (to cut and or pick) and work instructions for a product for manufacturing

Document – Written information used to describe how an activity is done.

Drawing – a 2D CAD drawing of a product and specification

FK – Full Kit (for manufacturing)

ISO – International Organization for Standardization

LPC – Larson Packaging Company

MP - Manufacturing partner (China, UK)

OB – Olive Branch Location (LPC)

On-Time Performance – The percent of orders that are shipped before or on the customer expectation

PO - Purchase Order

POOGI – Process of Ongoing Improvement

QMS - Quality Management System

Record – captured evidence of an activity having been done.

RFQ - Request for Quote

Spec – the customer and manufacturing requirements to build a product

TBR – To Be Released. A form and board where LPC assembles full kit before production

TT – Time Traveler. The form indicating work to be done and when as part of the VSS

VSS - Velocity Scheduling System

Velocity – the speed in which an order flows through the plant

Risk-Based Thinking Terminology

Risk – Negative effect of uncertainty **Opportunity** – Positive effect of uncertainty

Uncertainty – A deficiency of information related to understanding or knowledge of an event, its consequence, or likelihood. (Not to be confused with measurement uncertainty.)

Nonconforming Product Terminology

Rework – Efforts to bring nonconforming product into conformance through additional operations that <u>do not</u> alter the original design of the product.

Repair – Efforts to bring nonconforming product into conformance through additional operations that alter the original design of the product; this may be through the addition of material no specified in the original design, or through altering preexisting design features.

Scrap – The discard of nonconforming product in lieu of rework or repair.

Applicable Industry Standards

ASTM – American Society for Testing and Materials Customer specified standards

IPPC/ISPM-15 – International Plant Protection Committee/International Standards for Phytosanitary Measures-15, global standard and process for treatment of Solid Wood Packaging Materials (SWPM) to prevent the spread of pests.

ISO 9001:2015 – Quality Management System Requirements

ISTA – International Safe Transit Association Customer Specified Standards

MIL-SPEC – Military standards and designs applicable to the US Military. The basis for most west-coast crating and packaging. To some degree superseded by ASTM, but still in use

OSHA – Safety and Recycling

RoHS – EU Regulation: Lead-Free, stands for Restriction of Hazardous Substances

Reach – EU Regulation: Registration, Evaluation, Authorization and Restriction of Chemicals



4.0 Context of the Organization

4.1 Understanding the organization and its context

LPC has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company. For business-to-business customers and their delicate, sensitive, fragile and heavy products, we design and manufacture optimized Custom Industrial Packaging with short lead times delivering unmatched partnership as an extension of their team to optimize total value for all. We want to be the customer-preferred option for custom industrial packaging.

The graphic below lists our products and services.





Our principal locations are in Milpitas and San Diego, CA. We have a small manufacturing location in Olive Branch, MS and we work with manufacturing partners (MPs) to meet the needs of our customers globally.

We have identified seven strategic imperatives:

- We design, manufacture and sell Custom Industrial Packaging (CIP).
 Primarily shock and vibration protective packaging with a one-stop-shopping product mix. One-stop resource for custom industrial packaging.
- 2 Fast-fastest, shortest lead times to quote and deliver. Lean=Lead times, insource, speed, responsiveness.
- 3 Most approachable and talented design team-"Normal" professional, skilled, smart, creative and business/solutionoriented design team.

- 4 Bend over backwards customer service and partnership. Extension of your team.
- 5 High quality of materials and workmanship. Tight tolerances, precision. Quality System=Business /System. Use the technology QMS/ BMS, ACTV.
- 6 Sell directly with end customer relationships as much as possible and relationships with (distributor) sales reps as partners.
- 7 Value/solution approach to pricing.









We monitor the success and appropriateness of our strategies and tactics, discuss as part of management reviews and update as appropriate.

With respect to our QMS, KEY QUALITY OBJECTIVES are:

Quality Promise

✓ On Demand/On Time Delivery

✓ Total Customer Satisfaction

✓ Defect-free

KPI

- First Pass Yield % on FG (units)/Rework
- On Time Percentage
- Customer Survey/Overall Performance
- Net Promotor Score

4.2 Understanding the Needs and Expectations of Interested Parties

LPC has reviewed and analyzes key aspects as defined in 4.1 above, as well as the internal and external issues that are of concern to LPC's interested parties. Such issues are monitored and updated as appropriate, and discussed as a part of the management review. Context of the organization, interested parties and risk based thinking are documented via cloud based QMS Software TQA Cloud. This information is then used by senior management to determine the company's strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

4.3 Determining the Scope of the Quality Management System

LPC has determined the scope of the management system is:

Sell, design, prototype, manufacture, and deliver custom industrial packaging solutions including, but not limited to wooden crates, ATA and molded cases, fabricated foam, corrugated boxes, wooden pallets, and equipment packaging services to enable customers to safely ship their products to the point of use optimizing total cost and presentation, thereby achieving high levels of customer satisfaction, partnership, and loyalty.

The quality system applies to all processes, activities and employees within the company's principal manufacturing plant and HQ location. The facility is located at:

1000 Yosemite Dr. Milpitas, CA 95035	280 Cypress Lane El Cajon, CA 92020	customerservice@larsonpkg.com www.larsonpkg.com
Phone: 408-946-4971	Phone: 619-579-7166	
Fax: 408-946-0126	Fax: 619-579-7356	



The company claims no exclusions from the ISO 9001 standard.

LPC's manufacturing site at 20791 Stateline Rd Olive Branch, MS is excluded from the company quality system at this time; in the future, these may be incorporated into the company QMS, and this manual will be updated accordingly.

4.4 Quality Management System and Its Processes

The Quality Manual provides an overview of LPC's policies and procedures for various activities. We utilize TQA Cloud, a cloud-based QMS software, to document and maintain the QMS. This includes document control, QMS records such as approved suppliers, nonconforming outputs, corrective and preventative actions, as well as competence and training. Our BMS is our QMS. A copy of our quality manual is available for review by our customers, suppliers, employees, potential customers, third party auditors, and governmental and regulatory agencies, if applicable.

The LPC quality management system comprises the following documents:

- 1 Quality Manual
- 2 Standard Operating Procedures
- 3 Forms
- 4 Checklists

- 5 List of Documents
- 6 Industry specifications and material quality standards
- 7 Customer-supplied Engineering Documents

LPC has adopted a process approach for its business management system. By identifying the top-level processes within the company, and then managing each of these discretely, this reduces the potential for nonconforming Products or Services discovered during final processes or after delivery. Instead, nonconformities and risks are identified in real time, by actions taken within each of the top-level processes.

Note: not all activities are considered "processes" – the term "process" in this context indicates the activity has been elevated to a higher level of control and management oversight. The controls indicated herein are applicable only to the top-level processes identified.

Each process may be supported by other activities, such as tasks or subprocesses. Monitoring and control of top-level processes ensures effective implementation and control of all subordinate tasks or sub-processes.

Appendix A represents the overall flow of LPC's core business processes and how they interact with LPC's supporting QMS processes and procedures. Each of these core processes is summarized by a unique Turtle Diagram below:



Sales/Design & Quoting

INPUT		PROC	ESS	OUTPUT
 Customer requirements Industry standards Material and other requirement Design and manufacturing possibilities 	S	 CAD/CAM Cost estimation Pricing/quoting 		 > Work instructions > Cut sheets > Drawings > Quotes/pricing
WHAT - Resources			WHO- Human R	esources
Materials, Infrastructure, Equipment			Knowledge , Skill, Compe	etence, Safety Requirements
 Computer platform Materials, samples and catalogs Solidworks and other CAD and CAM software 	> vTiger CRM	ing prototype tools ction and	 > Sales/account manage > Designers/packaging > Ability to relate to cust understand their required 	engineers packaging understanding stomers and > Excel and CAD/CAM
HOW — Process Sequence	& Controls		MEASURES - Pe	erformance Indicators
Procedures, Instructions, Statutory Re	quirements		Key Performance Indicat	tors, Metrics, Analysis
 Capture customer requirements Produce sketch and cut sheet/ cost estimate draft Provide quote to customer 	required/fin Create work	ticle/get approval as alize design instructions for ing and specs for ervice	 Contribution margin 5 Throughput margin % \$ Throughput/hr 	

Order Acceptance/Processing – Customer Service

INPUT		PROCESS	OUTPUT
 Customer PO Sales Design 	> Order en > Custome	try er satisfaction	 > Work order > Production packet/work instructions
WHAT - Resources		WHO- Human R	Resources
Materials, Infrastructure, Equipment Communications Computing environment SAGE 100 ERP	 > Nsyteful > vTiger CRM > Product specs 		100) > Interaction and coordination
HOW – Process Sequence	& Controls	MEASURES - P	erformance Indicators
Procedures, Instructions, Statutory Re	quirements	Key Performance Indicat	tors, Metrics, Analysis
 > Capture customer requirements > Review requirements > Adjust requirements as required 	 > Order entry > Provide instructions to plant > Follow-up and invoice 	 Customer satisfactio On-time order % On-time case comple 	



Purchasing & Supplier Management

INPUT	PRO	CESS	OUTPUT
 > Design and manufacturing requirements > Customer orders > Inventory levels and requirements 	 > Supplier identific evaluation, and s > Quoting, purchas > Inventory manag > Supplier control a action requests 	selection sing/PO ement	 > Qualified and reliable vendors and suppliers-AVL > Optimal raw materials and other inventory > Well functioning facility
WHAT - Resources		WHO- Human R	esources
Materials, Infrastructure, Equipment		Knowledge , Skill, Compe	tence, Safety Requirements
 > SAGE 100 ERP system > Computing hardware > Procedures - purchasing and supplier management > Procedures - purchasing and supplier management 	ecifications and DMs	 MS Office and SAGE Familiarity with material markets 	
HOW – Process Sequence & Controls		MEASURES - Pe	erformance Indicators
Procedures, Instructions, Statutory Requirements		Key Performance Indicat	ors, Metrics, Analysis
and maintain AVL determine of	rack purchase orders	 > Gross margin % > Throughput % > Materials cost % 	

Manufacture & Ship

INPUT		PRO	CESS	OUTPUT
 > Raw materials > Purchased parts > Work order/time travelers > Work instructions/design spece 	cs	 > Receiving > Cutting > Velocity sched system 	 > Assembly > Quality checks > Shipping 	> Finished goods> Outbound logistics
WHAT - Resources			WHO- Human	Resources
Materials, Infrastructure, Equipment			Knowledge , Skill, Com	petence, Safety Requirements
 > Raw materials and purchased parts - on time > Sawing, CNC, nailing, adhering equipment > Manufacturing space and tables, conveyors > Accurate, complete work instructions and spec 		 > Plant management supervision > Understand VSS > Follow safety proce 	who can operate machinery and understand industry standards and practices	
HOW – Process Sequenc	e & Controls		MEASURES - I	Performance Indicators
Procedures, Instructions, Statutory	Requirements		Key Performance Indic	ators, Metrics, Analysis
 Schedule, detail planning Cutting/kitting Parts manufacturing and assembly 	 > Finishing ar > Ship 	nd quality check	 > First pass yield % > On-time delivery % > \$ Throughput/hr 	



We take a modern, perfectionist view towards managing and performing our processes related to "Plan, Do, Check, Act," but that embeds quality throughout the process, continually, not just the end.





5.0 Leadership

5.1 Leadership & Commitment

Larson Packaging Company is a flat, hierarchy-less organization where all employees are empowered and focused on achieving high levels of customer service and total customer satisfaction through Smart. Packaging. Fast. and continually improving processes, throughput/velocity, quality, and on-time deliveries.

Management's role is to maintain this flat, empowered organization that we call a Customer Success Team and support it with technology and culture to provide excellent customer service.



Total commitment to Smart. Packaging. Fast., Customer-Centric and Professional, extension of customer team, and values-based leadership in everything has enabled Larson Packaging Company to achieve high levels of customer satisfaction and loyalty. Further, LPC has developed and refined a robust business management system aligned with our QMS. This includes the use of:

- a) Theory of Constraints (TOC) and Throughput Accounting for decision making
- b) Values based Leadership
- c) Strategic thinking

- d) Sage ERP, MFG100
- e) Velocity Scheduling System (VSS)
- f) ISO 9000 and key objectives
- g) Sales Process Engineering (SPE)
- h) VTiger, CRM platform



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Responsibility	Assigned To
Ensuring that the management system conforms to applicable standards	CEO
Ensuring that the processes are delivering their intended outputs	Applicable process owner
Reporting on the performance of the management system and providing opportunities for improvement for the management system	CEO
Ensuring the promotion of customer focus throughout the organization	CEO
Ensuring that the integrity of the management system is maintained when changes are planned and implemented	CEO



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6.0 Planning

6.1 Actions to Address **Risks and Opportunities**

Note: LPC deviates slightly from the approach towards risk and opportunity presented in ISO 9001. Instead, LPC views "uncertainty" as neutral, but defines "risk" as a negative effect of uncertainty, and "opportunity" as a positive effect of uncertainty. LPC has elected to manage risks and opportunities separately, except where they may overlap. Formal risk management may not be utilized in all instances; instead, the level of risk assessment, analysis, treatment and recordkeeping will be performed to the level deemed appropriate for each circumstance or application.

LPC considers risks and opportunities when taking actions within the management system, as well as when implementing or improving the management system; likewise, these are considered relative to products and services. Risks and opportunities are identified as part of the "Context of the Organization Exercise" we have undertaken and documented, as well as throughout all other activities of the OMS.

Risks and opportunities are managed in accordance with the document Risk & **Opportunity Management.** This procedure defines how risks are managed in order to minimize their likelihood and impact, and how opportunities are managed to improve their likelihood and benefit.

LPC has two levels of quality objectives: the corporate "main" Quality Objectives defined in section 4.1 above, and process-level KPIs defined in the turtle diagrams of each process in section 4.4 above.

In all cases, the objectives have been developed in consideration that they:

- a) be consistent with the quality policy;
- b) be measurable;

- e) be monitored;
- c) take into account applicable requirements;
- d) be relevant to conformity of products and services and to enhancement of customer satisfaction:
- f) be communicated;
- g) be updated as appropriate.

6.3 Planning of Changes

6.2 Quality

Planning to

Objectives and

Achieve Them

Since our marketplace is dynamic, with changing competitive, customer and business needs, our overall performance of our BMS/QMS may change over time. Changes in the BMS/QMS may be identified and reviewed for continuing suitability and effectiveness in Management Review meetings, and acted on, as necessary.

Changes to the quality management system and its processes are carried out in a planned manner and can be initiated via the Corrective & Preventive Action Procedure and/or via Management Reviews. We take these processes very seriously and to our value of continual Improvement.



7.0 Support

7.1 Resources

7.1.1 General

Larson Packaging Company determines and provides the resources needed:

- a) to implement and maintain the management system and continually improve its effectiveness
- b) to enhance customer satisfaction by meeting customer requirements

We ensure through quality and financial plans that adequate resources are available for the implementation and improvement of the quality management system and the effective delivery of service. These include qualified personnel, facilities, equipment, infrastructure, information, and an appropriate and suitable working environment. Resource allocation is done with consideration of the capability and constraints on existing internal resources, as well as needs related to supplier expectations.

Resources and resource allocation are assessed during management reviews.

7.1.2 People

Senior management ensures that it provides sufficient staffing for the effective operation of the management system, as well its identified processes. Personnel requirements are identified, and appropriately qualified personnel are provided for management, performance of work and verification activities to ensure the effectiveness of the quality system and service delivery. Tasks are defined explicitly and appropriately trained staff are assigned to these duties.

7.1.3 Infrastructure

Larson Packaging Company provides suitable office and manufacturing and distribution facilities. These include appropriate space, production equipment, computer and communication systems, and supporting services. A preventive maintenance program is in place. LPC carries on its activities in office and plant facilities that are suitable for its needs and conform to local health, safety and environmental regulations.

LPC determines, provides and maintains the infrastructure needed to achieve conformity to product requirements Infrastructure includes, as applicable:

- a) buildings, workspace and associated facilities;
- b) invest in equipment and process improvement;
- c) process equipment, hardware and software;
- d) supporting services such as transport;
- e) information and communication technology.

Equipment is maintained per the procedure Preventive Maintenance.





7.1.4 Environment for the Operation of Processes

LPC provides a clean, safe and well-lit working environment. The Management Team of LPC manages the work environment needed to achieve conformity to product requirements. Specific environmental requirements for products are determined during quality planning and are documented in subordinate procedures, work instructions, or job documentation. Where special work environments have been implemented, these shall also be maintained per 6.3 above.

Human factors are considered to the extent that they directly impact on the quality of Products and Services.

Note: Social, psychological and safety aspects of the work environment are managed through activities outside of the scope of the management system. Only work environment aspects which can directly affect process efficiency or product and service quality are managed through the management system.

7.1.5 Monitoring and Measuring Resources

Where equipment is used for critical measurement activities, such as inspection and testing, these shall be subject to control and either calibration or verification; see the procedure **Calibration and Control of Measuring Equipment**.

Note: Calibration and measurement traceability is not employed for all measurement devices. Instead LPC determines which devices will be subject to calibration based on its processes, products and services, or in order to comply with specifications or requirements. These decisions are also based on the importance of a measurement, and considerations of risk.



7.1.6 Organizational Knowledge

LPC also determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. Knowledge is an integral part of key capabilities that LPC has or is developing. This may include knowledge and information obtained from:

- a) internal sources, such as lessons learned, experience and experimentation, feedback from subject matter experts, and/or intellectual property;
- b) external sources such as standards, trade groups and trade shows, academia, conferences, and/or information gathered from testing, customers or suppliers.

This knowledge is integrated into internal proprietary tools, guides and checklists, saved on a shared server, and captured and disseminated to various people in the organization. This knowledge shall be maintained and made available as necessary.

When addressing changing needs and trends, LPC shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge and expertise.

7.2 Competence	Staff members performing work affecting product quality are recruited, trained
	and evaluated as competent on the basis of appropriate education, training, skills
	and experience and work performance day-to-day. Employees receive an overview
	of the LPC QMS upon hire and are trained ongoingly. The documented procedure
	Training defines these activities in detail.

Note: the management system does not include other aspects of Human Resources management, such as payroll, benefits, insurance, labor relations or disciplinary actions.

7.3 Awareness	The LPC Quality Policy, customer complaints or issues, process issues, quality
	objectives, and successes are shared with all employees as needed via email, or
	in-person meetings.

7.4 CommunicationLPC communicates Quality to current and potential customers via our Quality Manual, sales outreach; email updates to suppliers through feedback, CAPAs and employees via email, postings or meetings. LPC communicates often and robustly with all parties and stakeholders at varied and appropriate intervals as determined by management and customer service.

7.5 Documented Information

The management system documentation includes both documents and records.

Note: the ISO 9001:2015 standard uses the term "documented information." LPC does not use this term, but instead relies on the terms "document" and "record" to avoid confusion. In this context the terms are defined by LPC as provided for in section 3.0 above. Documents and records undergo different controls as defined herein.



The extent of the management system documentation has been developed based on the following:

- a) The size of LPC
- b) Complexity and interaction of the processes
- c) Risks and opportunities
- d) Competence of personnel

Documents required for the management system are controlled in accordance with procedure **Control of Documents.** The purpose of document control is to ensure that staff have access to the latest, approved information, and to restrict the use of obsolete information. All documented procedures are established, documented, implemented and maintained on the Larson TQA Cloud.

A documented procedure **Control of Records** has been established to define the controls needed for the identification, storage, retrieval, protection, retention time, and disposition of quality records. This procedure also defines the methods for controlling records that are created by and/or retained by suppliers or required specifically by customers.

These controls are applicable to those records which provide evidence of conformance to requirements; this may be evidence of Product or Service requirements, contractual requirements, procedural requirements, or statutory/ regulatory compliance. In addition, quality records include any records which provide evidence of the effective operation of the management system.

Approved documents are uploaded on an internal shared drive. Besides online availability of documented information, printed documents are available in key areas of our plant and office for ease of use and effective implementation. These document sets are updated when new documents are added or existing documents are updated for improvement or compliance with current best practices.

Customer supplied part drawings and prints are protected online for each project, or as required by the customer. When necessary, customer supplied documents are shared with suppliers or partners to meet customer requirements.

Old documents are archived online, and marked obsolete. Completed quality records are filed in-office/online or at an offsite location for preservation and to meet customer requirements when specified.



8.0 Operation

8.1 Operational Planning and Control

LPC's QMS and processes needed for realization of its Products or Services are integrated into the core of its routine operations and what we do daily. LPC has customers who provide requirements for design and quotation. Salespeople and Packaging Engineers/Designers work together to ensure that customer requirements—including acceptable quality levels—have been identified and documented. Once a PO is received, sales, design, customer service, purchasing and operations ensure customer specified requirements are met.

Changes to operational processes can be initiated and are managed via the *Corrective & Preventive Action* procedure and/or via *Management Reviews*.

Outsourced processes and the means by which LPC controls them are defined in the documented procedure *Purchasing and Supplier Management*.

8.2 Requirements for Products and Services

LPC management, sales staff and design engineers maintain frequent and ongoing communication with interested parties to ensure requirements are identified and assessed. Interested parties include customers, suppliers, technical and regulatory bodies, and the community. Company personnel at all levels are expected to maintain currency of their technical and professional knowledge, and to participate in technical and regulatory bodies and the community as appropriate to the Company's activities.

We have designed and implemented processes to ensure the needs of customers are clearly and completely recorded, understood, defined and communicated to all parties, and that the appropriate resources are applied to deliver the agreed service. We provide products and services to meet the required outcomes and consider not only specified customer needs, but also technical standards, regulatory requirements, timeliness and other related factors.

Where we develop specifications to meet identified customer needs, we review these with the customer to ensure conformity. When required or appropriate, formal customer approval of such specifications is recorded. Where any order requirements differ from those previously expressed such differences are resolved with the customer before proceeding. Any subsequent changes to orders are communicated to all concerned.

Communication is maintained with customers through the sales process and through meetings and/or reviews if required by the order. All orders are subject to final review to confirm the product meets customer requirements. Any failures identified by these processes are referred to LPC management as appropriate, and if warranted may be subject to corrective actions.

We review customer requirements for each order and ensure customer specifications are documented, current and available to those responsible for service delivery. We ensure we are capable of meeting specified requirements at all times and may elect to decline orders that do not fall within our defined lines of business.



8.3 Design and Development of Products and Services

8.4 Control of Externally Provided Processes, Products and Services LPC provides design services for customers' parts and products as requested/ required by customers. Customers either furnish a part or a drawing along with specified requirements and leave it up to LPC to design the packaging, or they provide a drawing or concept and request a quote.

These activities are further defined in the document **Sales Design and Quoting** for most products that are manufactured. In some cases, customers are looking for just a design service. These activities are also defined in the **Sales Design and Quoting** procedure. These procedures address design and development planning, inputs, controls, outputs and changes.

LPC manufactures the vast majority of its products in-house. In some cases, precut parts or manufactured assemblies are sourced from qualified suppliers. And in some cases, LPC uses Manufacturing Partners in different locations to provide our customers finished goods. In all of these cases, LPC ensures that purchased Products conform to specified purchase requirements. The type and extent of control applied to the supplier and the purchased products or services are dependent on the effect on subsequent Product realization or the final product.

LPC evaluates and selects suppliers based on their ability to supply products and services in accordance with the organizations and customer requirements. Criteria for selection, evaluation and re-evaluation are established.

Purchases are made via the release of formal purchase orders and with drawings and specs which clearly describe what is being purchased along with drawings and specs for parts the Partner may need to source on their own. Received products or services are then verified against requirements to ensure satisfaction of requirements. Suppliers who are not providing conforming products or services may be requested to conduct formal corrective action.

LPC Management, sales personnel, packaging designers and customer service all work with customers and manufacturing/supply partners in identifying and implementing proper controls which may include supplying drawings and specs, establishing quality levels, implementing work instructions, evaluating first article inspection reports, quality of products, outgoing product inspection and CAPA collaboration.

If necessary, LPC has and will deploy its own management and quality staff to the manufacturing partner's facility to ensure product meets customer requirements.

These activities are further defined in the documents *Purchasing and Supplier Management* procedure and *Receiving* procedure.

8.5 Production and Service Provision

Customer-related and part-specific information is maintained by LPC. Customer property primarily includes prints and drawings, or usage or performance standards, generally in electronic media. Only the current version of customer supplied documents shall be used when ordering or building parts or verifying performance. Similarly, only the current LPC documentation is available for use in manufacturing. The documented procedures we use for production define these methods in detail.



	LPC exercises care with customer or supplier property while it is under the organization's control or being used by the organization. Upon receipt, such property is identified, verified, protected and safeguarded. If any such property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer or supplier and records maintained.
	For customer intellectual property, including customer furnished data used for design, production and / or inspection, this is identified by customer and maintained and preserved to prevent accidental loss, damage or inappropriate use.
	This activity is defined in greater detail in the document <i>Control of Third-Party Property</i> procedure.
	LPC ensures that product or other process outputs are adequately identified, and properly preserved during internal processing, storage and delivery. This preservation includes identification, handling, packaging, storage, and protection.
	LPC performs "pack jobs" as a post-delivery activity; this involves LPC sending its staff to assist or perform actual packing of customer product into LPC-provided packaging products. In such cases these activities will be defined in normal job requirements documents (work orders, etc.) with additional instructions written as needed. Evidence of completion of the job is maintained as a record, and the customer approves the work before LPC leaves the site.
	LPC reviews and controls both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with all requirements.
	Process change management is defined in the document Corrective and Preventive Action as well as Management Review .
	Documents are changed in accordance with procedure Control of Documents .
8.6 Release of Products and Services	Acceptance criteria for Products are defined by industry standard practice or where applicable in customer-specific appropriate subordinate documentation. When required by the customer, reviews, inspections and tests are conducted at appropriate stages to verify that the requirements have been met. This is done before Products are released or services are delivered.
8.7 Control of Nonconforming Outputs	LPC ensures that materials, products or other process outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. If shipment quantity is affected, customer shall be notified and provide

authorization to ship with deviation.

The controls for such nonconformances are defined in *Control of NC Product*.



9.0 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

LPC has determined which aspects of its quality management system must be monitored and measured, as well as the methods to utilize and records to maintain, within this Quality Manual and subordinate documentation.

Monitoring and measurement of the processes, as defined in 4.4 above, ensure that the LPC CEO/COO evaluates the performance and effectiveness of the quality management system itself.

As one of the measurements of the performance of the management system, LPC monitors information relating to customer perception as to whether the organization has met customer requirements. Management and sales and customer service staff gather customer feedback about various processes and to identify opportunities for improvement and better performance. Our teams are in frequent, if not constant contact to ensure customer satisfaction.

Data from various sources are gathered and analyzed to review customer satisfaction, effectiveness of QMS, risk management, performance of suppliers, partners and supply chain and opportunities for improvement in QMS for ongoing suitability and effectiveness.

The corrective and preventive action system shall be used to develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations and assess the effectiveness of the results.

9.2 Internal Audit

LPC conducts internal audits at planned intervals, at least annually, to determine whether the management system conforms to contractual and regulatory requirements, to the requirements of ISO 9001, and to management system requirements. Audits also seek to ensure that the management system has been effectively implemented and is maintained.

These activities are defined in the document Internal Auditing.

9.3 Management Review

The LPC Management Team reviews the management system, at planned intervals, generally bi-annually, to ensure its continuing suitability, adequacy and effectiveness. The review includes assessing opportunities for improvement, and the need for changes to the management system, including the **Quality Policy** and quality objectives.

Management review frequency, agenda (inputs), outputs, required members, actions taken, and other review requirements are defined in the documented procedure *Management Review*.

Records from management reviews are maintained.



10.0 Improvement

10.1 General

LPC uses the management system to improve its processes, products and services. Such improvements aim to address the needs and expectations of customers as well as other interested parties, to the extent possible.

Improvement shall be driven by an analysis of data related to:

a) conformity of products and services;b) the degree of customer satisfaction;

c) the performance and effectiveness

of the management system,

including improvements;

- d) the effectiveness of actions taken to address risks and opportunities;
- e) the performance of external providers;

10.2 Nonconformity and Corrective Action

LPC takes corrective action to eliminate the cause of nonconformity in order to prevent recurrence. Likewise, the company takes preventive action to eliminate the causes of potential nonconformities in order to prevent their occurrence.

When a nonconformity has been identified by a customer, through internal audits, or reported by anyone within the scope of the QMS, the non-conformity must be clearly defined, analyzed and remedied. Customer complaints shall be handled according to the *Corrective and Preventive Action* procedure.

Each customer reported nonconformity shall be addressed according to the *Corrective and Preventive Action*. Once the nonconformity has been verified, to address customer concerns, containment action ensures any existing material is verified for meeting customer requirements and immediate corrective action is taken as necessary to ensure compliance and customer satisfaction. At that point, root cause analysis is performed to effectively remedy the nonconformance and preventive action ensures the problem is remedied at the process level in operations. Any subsequent process change must be verified for effectiveness and QMS updated.

10.3 Continual Improvement

Through the process effectiveness reviews, done as part of Management Review, and ad hoc as issues arise, LPC works to continually improve the suitability, adequacy and effectiveness of the quality management system. This includes continually seeking opportunities for improvement.



Appendix

A - Overall Process Sequence & Interaction





B - ISO9001:2015 Certificate











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