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# ISO 9001:2015

## Quality Management System

### Manual

#### LND, INC. PROPRIETARY INFORMATION

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## Quality System Manual - Section 00

### QM INDEX, QMS FORMS, AND REVISION STATUS

Issued by: **Quality Assurance**

Eff. Date: 3/11/20

Rev.: **O**

Pg. 2 of 52

SECTION 00 – QM INDEX, QMS FORMS, AND REVISION STATUS

Rev. **O**

SECTION 1 – SCOPE

Rev. E

1.1 About LND Quality Manual

1.2 Company Background

1.3 Products and Services

1.4 Exclusions

SECTION 2 – NORMATIVE REFERENCES

Rev. J

2.1 Regulatory Requirements

2.2 Standards and Guidelines

SECTION 3 - TERMS AND DEFINITIONS

Rev. D

SECTION 4 – CONTEXT OF THE ORGANIZATION

Rev. **G**

4.1 Understanding the Organization and its Context

4.2 Understanding the Needs and Expectations of Interested Parties

4.3 Determining the Scope of the Quality Management System

4.4 Quality Management System and its Processes

SECTION 5 - LEADERSHIP

Rev. **G**

5.1 Leadership and Commitment

5.1.1 General

5.1.2 Customer Focus

5.2 Policy

5.2.1 Establishing the Quality Policy

5.2.2 Communicating the Quality Policy

5.3 Organizational Roles, Responsibilities and Authorities

5.3.1 Management Representative

SECTION 6 - PLANNING

Rev. **H**

6.1 Actions to Address Risks and Opportunities

6.2 Quality Objectives and Planning to Achieve Them

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Spencer B Neyland

5 May 2020

### 6.3 Planning of Changes

## SECTION 7 – SUPPORT

Rev. **F**

### 7.1 Resources

#### 7.1.1 General

#### 7.1.2 People

#### 7.1.3 Infrastructure

#### 7.1.4 Environment for the Operation of Processes

#### 7.1.5 Monitoring and Measuring Resources

##### 7.1.5.1 General

##### 7.1.5.2 Measurement Traceability

#### 7.1.6 Organizational Knowledge

### 7.2 Competence

### 7.3 Awareness

### 7.4 Communication

### 7.5 Documented Information

#### 7.5.1 General

#### 7.5.2 Creating and Updating

#### 7.5.3 Control of Documented Information

## SECTION 8 - OPERATION

Rev. **G**

### 8.1 Operational Planning and Control

### 8.2 Requirements for Products and Services

#### 8.2.1 Customer Communication

#### 8.2.2 Determining the Requirements for Products and Services

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

#### 8.2.4 Changes to Requirements for Products and Services

### 8.3 Design and Development of Products and Services

#### 8.3.1 General

#### 8.3.2 Design and Development Planning

#### 8.3.3 Design and Development Inputs

#### 8.3.4 Design and Development Controls

- 8.3.5 Design and Development Outputs
- 8.3.6 Design and Development Changes
- 8.4 Control of Externally Provided Processes, Products and Services
  - 8.4.1 General
  - 8.4.2 Type and Extent of Controls
  - 8.4.3 Information for External Providers
- 8.5 Production and Service Provision
  - 8.5.1 Control of Production and Service Provision
  - 8.5.2 Identification and Traceability
  - 8.5.3 Property Belonging to Customers or External Providers
  - 8.5.4 Preservation
  - 8.5.5 Post-delivery Activities
  - 8.5.6 Control of Changes
- 8.6 Release of Products and Services
- 8.7 Control of Nonconforming Outputs

## SECTION 9 – PERFORMANCE EVALUATION

Rev. B

- 9.1 Monitoring, Measurement, Analysis and Evaluation
  - 9.1.1 General
  - 9.1.2 Customer Satisfaction
  - 9.1.3 Analysis and Evaluation
- 9.2 Internal Audit
- 9.3 Management Review
  - 9.3.1 General
  - 9.3.2 Management Review Inputs
  - 9.3.3 Management Review Outputs

## SECTION 10 – IMPROVEMENT

Rev. C

- 10.1 General
- 10.2 Nonconformity and Corrective Action
- 10.3 Continual Improvement

	<b>QM INDEX, QMS FORMS, AND REVISION STATUS</b>			
	Quality System Manual	Section 00	Rev.: O	Pg. 5 of 52

#### ATTACHMENTS

1      ISO9001:2015 Comparison to ISO9001:2008      Rev. A

**NOTE:**      For a complete listing of all current Quality Operational Procedures (QOP) and Work Instructions (WI) related to the LND QMS refer to LND procedure 1-911-0091.

### QUALITY SYSTEM FORMS

1-900-0012	Re-graded Tube Assemblies
1-900-0017	Design Specification Sheet
1-901-0001	Plant Maintenance Work Order
1-901-0003	Scrap-Do Not Salvage
1-901-0007	Supplier Certification
1-904-0004	Customer Property Inventory
1-911-0004	Material Rejection Report (MRR)
1-911-0005	Supplier Corrective Action Request (SCAR)
1-911-0006	Engineering Change Request (ECR)
1-911-0008	Calibration Record Card
1-911-0009	Employee Qualifications
1-911-0028	Engineering Change Order (ECO)
1-911-0032	Audit Nonconformity Report (QF-82-02-2)
1-911-0033	Supplier Quality System Survey
1-911-0034	Corrective Action Request (QF-85-03-1)
1-911-0038	Conditional Acceptance Authorization and Validation
1-911-0039	Internal Audit Checklist
1-911-0040	Internal Audit Plan (QF-82-02-1)
1-911-0064	Quality Audit of LND Suppliers
1-911-0084	In-House Calibration Certificate
1-911-0086	FMEA Worksheet
1-913-0004	Customer Return Disposition Log
1-914-0004	WIP Output Log
1-915-0013	Training Record
1-511-0069	Initial Electrical Test Card
1-511-0062	NCR Tag
1-511-0075	Rework Tag
QF-85-02-1	Customer Complaint

**QM INDEX, QMS FORMS, AND REVISION STATUS****Quality System Manual****Section 00****Rev.: O****Pg. 7 of 52****Quality System Manual Revisions**

<b>REV.</b>	<b>PAGES</b>	<b>CHANGE REQUEST #</b>	<b>DATE</b>	<b>AUTHORIZED BY</b>
00	All	Initial Release	10/18/07	S. Neyland
01	Incorporated	ECR 852	8/21/09	S. Neyland
02	Incorporated	ECR 1260	11/1/10	S. Neyland
03	Incorporated	ECR 1338	2/11/11	S. Neyland
04	Incorporated	ECR 1530	11/30/11	S. Neyland
05	Incorporated	ECR 1739	2/12/13	S. Neyland
06	Incorporated	ECR 1866	9/27/13	S. Neyland
07	Incorporated	ECR 2143	8/25/14	S. Neyland
08	Incorporated	ECR 2340	9/8/15	S. Neyland
09	Incorporated	ECR 2531	9/1/16	S. Neyland
10	Incorporated	ECR 2695	12/14/17	S. Neyland
11	Incorporated	ECR 2757	1/30/18	S. Neyland
12	Incorporated	ECR 2987	5/21/19	S. Neyland
13	Incorporated	ECR 3051	9/17/19	S. Neyland
14	Add new PRP10 to process matrix and revise text as required.	ECR 3106	3/11/2020	S. Neyland

	QM INDEX, QMS FORMS, AND REVISION STATUS			
	Quality System Manual	Section 00	Rev.: O	Pg. 8 of 52

### Quality System Manual Availability

Copies of this manual are available online at the LND, Inc. website ([www.LNDINC.com](http://www.LNDINC.com)) for downloading and also on the LND intranet PICS system affording access to all LND employees. Printed copies of this manual are considered to be uncontrolled and the information obsolete immediately upon being printed.





## Quality System Manual - Section 1

### SCOPE AND EXCLUSIONS

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Eff. Date: **1/31/18**

Rev.: **E**

Pg. **9** of **52**

#### 1.1 About LND Quality Manual

**LND, Inc.** Quality System Manual provides general policies and procedures for the manufacturing, packaging, testing, storage, and distribution of products and services. The **LND, Inc.** Quality System Manual is a top-tier quality document for **LND, Inc.** located at 3230 Lawson Blvd, Oceanside, NY 11572.

#### 1.2 Company Background

**LND, Inc.** designs, engineers and manufactures gas-filled nuclear radiation detectors. Since 1964, LND has developed a product line that encompasses all the commercial, scientific and military applications for nuclear radiation detectors, and we have sold over two million detectors worldwide.

**LND, Inc.** developed and implemented a quality management system to demonstrate its ability to provide products and services that consistently meet customer, statutory and regulatory requirements, and to address customer satisfaction through the effective application of the quality management system, including continual improvement and the prevention of nonconformities. The quality management system complies with the international standard ISO 9001:2015 and government specification MIL-PRF-1N.

#### 1.3 Products and Services

LND's product line includes Geiger-Mueller Tubes, Energy Compensated Geiger-Mueller Tubes, End- and Side-Window X-ray Proportional Counters, Position Sensitive Detectors, BF<sub>3</sub> and <sup>3</sup>He Neutron Proportional Detectors, Ionization Chambers, Fission Counters, Neutron Beam Monitors, Flow Counters, and Polymer Window Proportional Counters.

Applications for LND products include, but are not limited to, Health Physics, Analytical Instrumentation, Environmental and Air Quality Monitoring, Personnel Monitoring, Power Plant Applications, Industrial Gauging, Medical Instrumentation, High Energy Physics Research, X-Ray Spectroscopy, Non-Destructive Testing, Homeland Security, and Space Exploration.

#### 1.4 Exclusions

No exclusions taken.

Approved by/date:

Spencer B. Neyland

27 April 2018



## Quality System Manual - Section 2

### NORMATIVE REFERENCES

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Rev.: **J**

Pg. **10** of **52**

#### 2.1 REGULATORY REQUIREMENTS

10CFR50, Appendix B: Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

15CFR Parts 730 – 774: Export Administration Regulations (EAR)

MIL-PRF-1: Performance Specification; Electron Tubes, General Specifications for

49CFR Parts 106, 107 and 171 – 180: Pipeline and Hazardous Materials Administration, Department of Transportation

International Civil Aviation Organization (ICAO) – Technical Instructions for the Safe Transport of Dangerous Goods

International Maritime Dangerous Goods Code (IMDG)

ADR/RID Transportation Regulations (EU)

IATA Dangerous Goods Regulations

2011/65/EU and EU 2015/863 – Restrictions on Hazardous Substances II & III (RoHS) Directives

2012/19/EU – Waste Electrical and Electronic Equipment (WEEE) Directive

EC/1907/2006 – Registration, Evaluation and Authorization of Chemicals (REACH) Directive

Dodd-Frank Wall Street Reform and Consumer Protection Act – Section 1502, Conflict Minerals

#### 2.2 STANDARDS AND GUIDELINES

International Standard ISO9001:2015: Quality management systems - Requirements

American National Standard ANSI/ISO/ ASQ Q9000-2015: Quality management systems-Fundamentals and vocabulary

American National Standard ANSI/ISO/ ASQ Q9004-2009: A quality management approach-Managing for the sustained success of an organization

ISO 10002-2014: Quality Management - Customer Satisfaction – Guidelines for complaint handling in organization

ISO 11118-2015: Gas cylinders – Non-refillable metallic gas cylinders-Specification and test method

ISO 19011-2018: Guidelines for auditing management systems

**Approved by/date:**

Spencer Neyland

22 May 2019



## Quality System Manual - Section 3

### TERMS AND DEFINITIONS

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Rev.: **D**

Pg. **11** of **52**

- 3.1 **Audit:** Systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.
- 3.2 **Audit Criteria:** Set of policies, procedures or requirements used as a reference against which objective evidence is compared.
- 3.3 **Audit evidence:** Documented information, statements of fact or other information, which are relevant to the audit criteria and verifiable.
- 3.4 **Competence:** Ability to apply knowledge and skills to achieve intended results.
- 3.5 **Context of the organization:** Combination of internal and external issues that can have an effect on an organization's approach to developing and achieving its objectives.
- 3.6 **Continual improvement:** Recurring activity to enhance performance.
- 3.7 **Correction:** Action taken to eliminate a detected nonconformity.
- 3.8 **Corrective action:** Action to eliminate the cause of nonconformity and to prevent recurrence.
- 3.9 **Customer owned property:** Any type of part, sub-assembly, fixture, accessories, manuals, drawings, computers, software, shipping containers that belong to a customer.
- 3.10 **Customer satisfaction:** Customer's perception of the degree to which the customer's expectations have been fulfilled.
- 3.11 **Defect:** Nonconformity related to an intended use or specific use.
- 3.12 **Document:** Information and the medium on which it is contained.
- 3.13 **Documented information:** Information required to be controlled and maintained by an organization and the medium on which it is contained.
- 3.14 **External provider:** Organization that provides a product or a service.
- 3.15 **Interested party:** Person or organization that can be affected, be affected by, or perceive itself to be affected by a decision or activity.
- 3.16 **Nonconformity:** Nonfulfillment of a requirement.
- 3.17 **Outsource:** Make an arrangement where an external organization performs part of an organization's function or process.
- 3.18 **Procedure:** Specific way to carry out an activity or a process.

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- 3.19     **Process:** Set of interrelated or interacting activities that use inputs to deliver an intended result.
- 3.20     **Products and services:** Output of an organization that can be produced without any transaction taking place between the organization and the customer.
- 3.21     **Quality:** Degree to which a set of inherent characteristics of an object fulfills requirements.
- 3.22     **Quality assurance:** Part of quality management focused on providing confidence that quality requirements will be fulfilled.
- 3.23     **Quality control:** Part of quality management focused on fulfilling quality requirements.
- 3.24     **Quality improvement:** Part of quality management focused on increasing the ability to fulfill quality requirements.
- 3.25     **Quality management:** Coordinated activities to direct and control an organization with regard to quality.
- 3.26     **Quality policy:** Overall intentions and direction of an organization related to quality as formally expressed by top management.
- 3.27     **Record:** Document stating results achieved or providing evidence of activities performed.
- 3.28     **Risk and opportunity action:** Action to eliminate the cause of a potential nonconformity or other potential undesirable situation.
- 3.29     **Service:** Output of an organization with at least one activity necessarily performed between the organization and the customer.
- 3.30     **Top management:** Person or group of people who directs and controls an organization at the highest level.
- 3.31     **Validation:** Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.
- 3.32     **Verification:** Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.



## Quality System Manual - Section 4

### CONTEXT OF THE ORGANIZATION

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Rev.: G

Pg. 13 of 52

#### 4.1 Understanding the Organization and its Context

- 4.1.1 **LND, Inc.** identifies the processes needed for the Quality Management System and their application per the Process Flow Diagram and the Process Map Diagram in paragraph 4.4 of this manual.
- 4.1.2 **LND, Inc.** determines the sequence and interactions of processes by carefully analyzing processes, systems, and procedures per Operational Procedure **QOP 84-01, Analysis of Data**. Documented information of these process sequence and interactions may be in various forms, such as; flowcharts, memoranda, and other internal documents.
- 4.1.3 **LND, Inc.** determines criteria and methods to ensure Quality Management System processes based on nature, relative importance, and priority. These methods and criteria are documented as per Operational Procedure **QOP 56-01, Management Review**.
- 4.1.4 **LND, Inc.** ensures the availability of resources and information necessary to support the operation and monitoring of these processes per Operational Procedures **QOP 62-01, Competence, Awareness and Training**, and **QOP 63-01, Equipment Maintenance**.
- 4.1.5 **LND, Inc.** monitors, measures, and analyzes these processes per Operational Procedure **QOP 74-01, Evaluation and Monitoring**.
- 4.1.6 **LND, Inc.** implements actions necessary to achieve planned results per Operational Procedure **QOP 85-03, Corrective Action**.
- 4.1.7 **LND, Inc.** performs risk assessments and takes action to address these risks and opportunities per LND procedure **1-911-0095, Risk Analysis**.
- 4.1.8 **LND, Inc.** shall determine external and internal issues that are relevant and have an impact on the Quality Management System. These issues are addressed with senior management during the course of the Management Review process.

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

- 4.2.1 **LND, Inc.** monitors and reviews the needs of interested parties during the course of the Management Reviews. Refer to LND procedure **1-911-0099, Interested Parties**.

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

- 4.3.1 **LND, Inc.** quality management system is designed to meet the requirements of our commercial and government customers per ISO9001:2015 and MIL-

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5 May 2020

PRF-1.

- 4.3.2 While not required by the standard, **LND, Inc.** maintains a Quality System Manual as a top-level or Level 1 document. **LND also maintains documented** policies, objectives, and organization interaction of processes per Operational Procedure ***QOP 42-01, Control of Documents***.

**LND, Inc.** Quality Operational Procedures (QOPs) and documents required by the ISO 9001 standard are Level 2 documents.

**LND, Inc.** work instructions, engineering drawings, testing procedures, manufacturing specifications, and other technical documentation that describe product manufacture, servicing processes, and flowcharts are Level 3 documents.

**LND, Inc.** 's production records, test records, training records, internal and external audit reports, and other quality records, etc. are Level 4 documents.

#### 4.3.3 Quality System Manual

**LND, Inc.** maintains a Quality System Manual that is reviewed over the course of a year during the Management Review process. Any changes/revision to the manual can only incorporated by the QA Manager as part of LND procedure ***1-900-0007, Engineering Changes***. All revision change requests must be reviewed and signed by the persons listed in the Engineering Changes procedure.

#### 4.3.4 Scope

The scope of this Quality Management System includes the design and manufacturing of nuclear radiation detectors.

#### 4.3.5 Applicability

In total, **LND, Inc.** applies all elements of the ISO 9001:2015 standard.

### 4.4 Quality Management System and its processes

The Quality Management System is designed as a system of interrelated processes. All main activities of the system are defined as Quality System Processes (QSPs) and are grouped into the following four categories (refer to the Process Matrix and Process Map in this section of the Quality Manual):

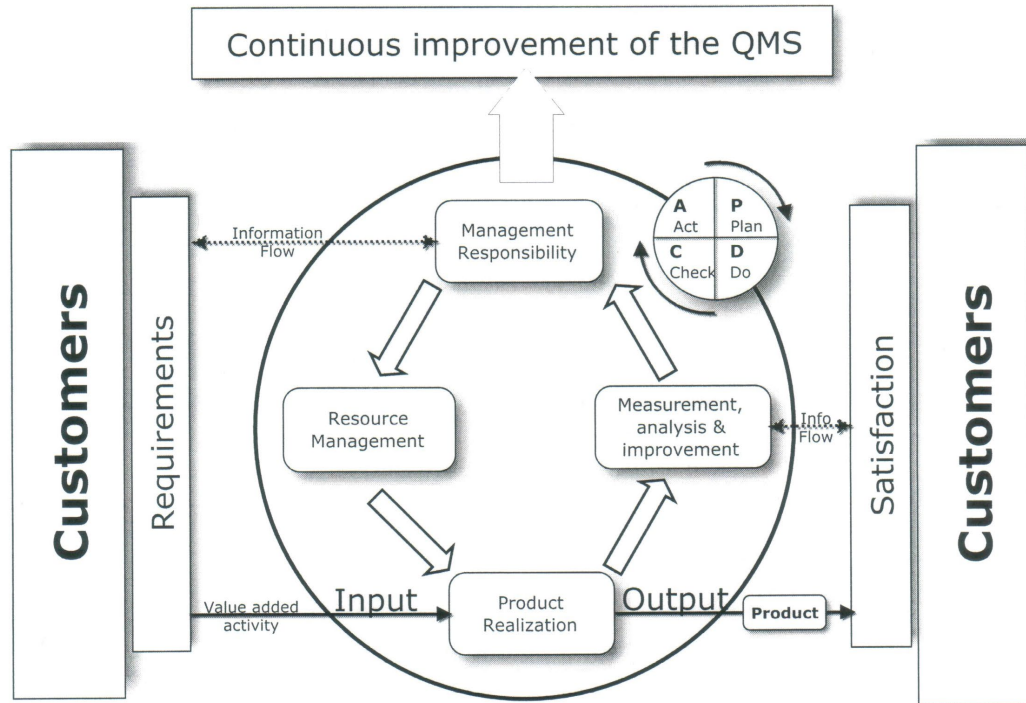
- Product Realization Processes (PRP),
- Measurement, Analysis and Improvement Processes (MIP),
- Management Responsibility Processes (MRP), and
- Resource Management Processes (RMP)

These processes are organized as Plan-Do-Check-Act (PDCA) loops.

The sequence and interrelation between the four groups and individual QSPs are illustrated in the Processes Map diagram. For a detailed illustration of sequence and interaction production processes, including key process

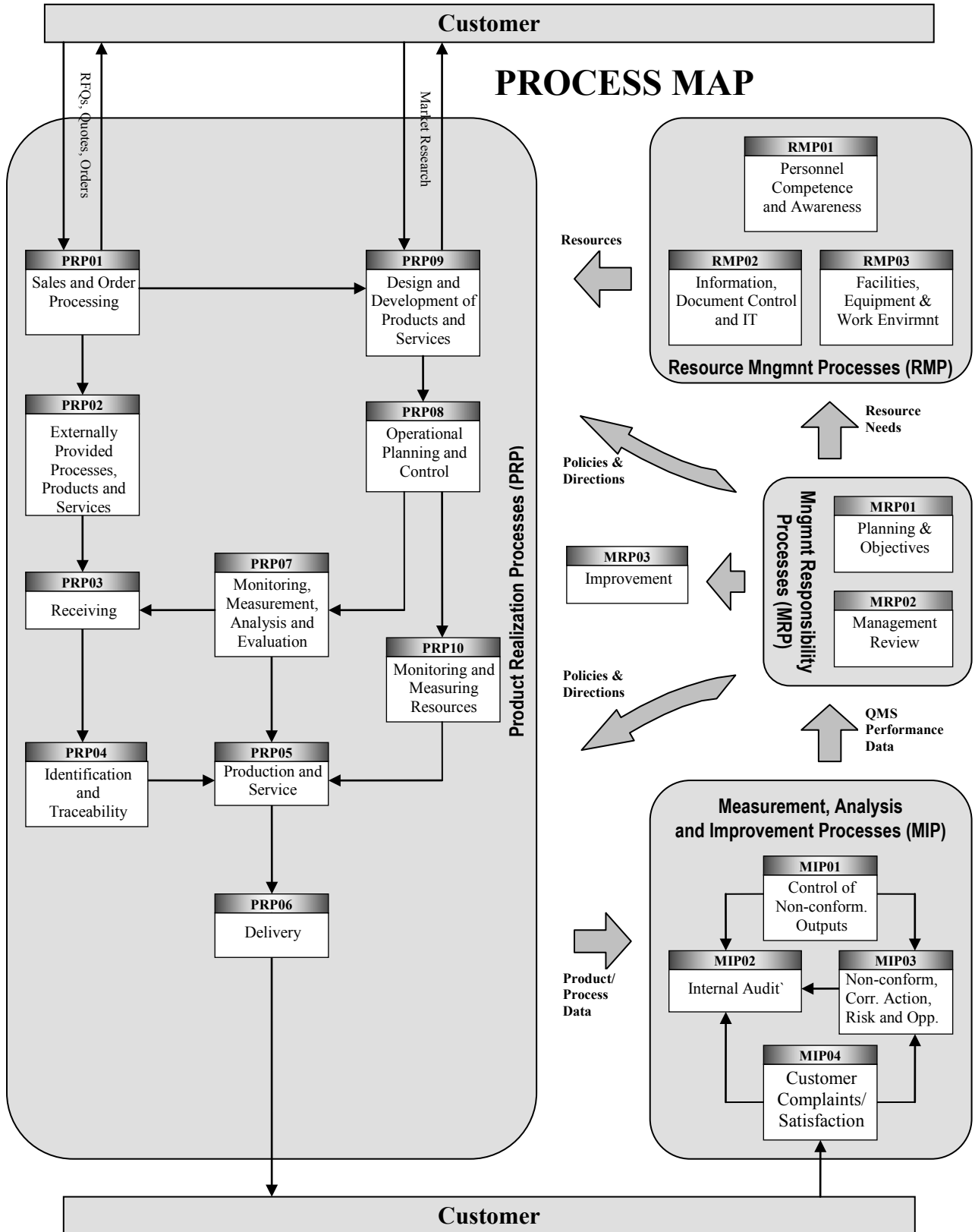
indicators, refer to Operational Procedure ***QOP-41-01, Production Process***.

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



**The Quality Management System (QMS)  
Process Flow Diagram**







## PROCESS MAP MATRIX

PRODUCT REALIZATION PROCESSES (PRPs)	
<b>Sales and Order Processing</b>	
<b>Purpose</b>	To determine customer requirements, prepare bids and quotations, submit tenders, and take orders from, or enter into contracts with, customers.
<b>Process Owner</b>	Sales
<b>Sub-Processes</b>	<ul style="list-style-type: none"> <li>• Determining products and services requirements</li> <li>• Determining customer requirements</li> <li>• Evaluating capability and capacity to meet requirements</li> <li>• Preparing quotations, bids and tenders</li> <li>• Entering orders (or signing contracts)</li> <li>• Receiving, entering and processing change orders</li> <li>• Providing products and services information</li> </ul>
<b>Design and Development of Products and Services</b>	
<b>Purpose</b>	To design and develop products and services meeting the design input requirements.
<b>Process Owner</b>	Engineering
<b>Sub-Processes</b>	<ul style="list-style-type: none"> <li>• Planning and scheduling design projects</li> <li>• Reviewing and controlling design input</li> <li>• Performing design activities</li> <li>• Conducting design reviews</li> <li>• Establishing design output documented information</li> <li>• Verifying and validating products and services designs</li> <li>• Controlling design changes</li> </ul>
<b>Production/Quality Planning</b>	
<b>Purpose</b>	To plan and develop processes needed for manufacturing and verification of products and services.
<b>Process Owner</b>	Engineering
<b>Sub-Processes</b>	<ul style="list-style-type: none"> <li>• Determining quality objectives and requirements for products and services</li> <li>• Developing, validating and documenting production processes (process sheets, equipment setup instructions, tooling specifications, operator instructions, etc.)</li> <li>• Establishing products and services acceptance criteria and products and services verification requirements (measuring, inspections, tests, etc)</li> </ul>
<b>Externally Provided Processes, Products and Services</b>	
<b>Purpose</b>	To select qualified external providers and to purchase from them materials, components, and services necessary for the manufacture and delivery of the products and services (for full scope of application refer to 1-901-0005, LND Supplier Manual).
<b>Process Owners</b>	Purchasing / Quality
<b>Sub-Processes</b>	<ul style="list-style-type: none"> <li>• Evaluating and selecting external providers</li> <li>• Maintaining a list of approved external providers (approved vendor list)</li> <li>• Preparing, reviewing and issuing purchasing documented information</li> <li>• Communicating with external providers regarding their quality performance (notifications, requests for corrective actions, etc.)</li> </ul>
<b>Receiving</b>	

	QUALITY MANAGEMENT SYSTEM			
	Quality System Manual	Section 4	Rev.: G	Pg. 18 of 52

<b>Purpose</b>	To receive purchased products and services, visually verify their conformity, and mark/label products with their identification and/or acceptance status, as applicable.
<b>Process Owner</b>	Receiving
<b>Sub-Processes</b>	<ul style="list-style-type: none"> <li>• Receiving purchased products</li> <li>• Visually inspecting incoming products</li> <li>• Applying and/or recording product identification and traceability of incoming products</li> </ul>
<b>Identification and Traceability</b>	
<b>Purpose</b>	To receive, store and issue materials, components and parts to be incorporated into finished products and services.
<b>Process Owner</b>	Stock Room
<b>Sub-Processes</b>	<ul style="list-style-type: none"> <li>• Operating and maintaining storage areas</li> <li>• Identifying and protecting product in storage</li> <li>• Maintaining special storage conditions/environment</li> <li>• Operating and maintaining the inventory management system</li> </ul>
<b>Production and Services</b>	
<b>Purpose</b>	To manufacture products conforming to applicable requirements.
<b>Process Owner</b>	Production
<b>Sub-Processes</b>	<ul style="list-style-type: none"> <li>• Carrying out manufacturing processes</li> <li>• Monitoring and controlling manufacturing processes</li> <li>• Establishing and maintaining production documented information</li> <li>• Training process operators and technicians (on-the-job)</li> <li>• Maintaining production equipment and tooling</li> </ul>
<b>Delivery</b>	
<b>Purpose</b>	To deliver products to customers and distributors.
<b>Process Owner</b>	Shipping
<b>Sub-Processes</b>	<ul style="list-style-type: none"> <li>• Processing shipping orders</li> <li>• Packaging and labeling product for shipping</li> <li>• Dispatching or shipping products</li> <li>• Establishing and maintaining shipping and distribution documented information</li> </ul>
<b>Monitoring, Measurement, Analysis and Evaluation</b>	
<b>Purpose</b>	To verify conformity of products and services, evaluate the effectiveness and efficiency of the quality management system.
<b>Process Owner</b>	Quality
<b>Sub-Processes</b>	<ul style="list-style-type: none"> <li>• Monitoring quality performance of external providers</li> <li>• Verifying purchased product (QC inspection)</li> <li>• Monitoring, measuring, and testing products (in-process and final)</li> <li>• Verifying inspection status identification</li> <li>• Analyzing and evaluating results of internal, third-party and customer audits</li> <li>• Collecting and analyzing quality performance data</li> <li>• Releasing products and services</li> <li>• Identifying nonconforming products and services</li> </ul>
<b>Monitoring and Measuring Resources</b>	
<b>Purpose</b>	Determining the suitability and fitness for the purpose of measuring instruments, selecting the correct monitoring or measuring resource, and maintaining the monitoring or measuring resource that preserves its ability to make measurements.
<b>Process Owner</b>	Quality

<b>Sub-Processes</b>	<ul style="list-style-type: none"> <li>Retain documented information of calibrations and verifications (Equipment Inventory List and Calibration Record Cards)</li> <li>Identify calibration status (label on device and Calibration Record Card)</li> <li>Prevent unauthorized adjustments (calibration seals remain intact)</li> <li>Checking previous calibration results when a device is reported out-of-calibration.</li> <li>Create, maintain and make available calibration procedures (PICS system)</li> <li>Inducting new monitoring or measuring resources into the calibration program</li> <li>Create Calibration record Cards for monitoring and measuring resources</li> <li>Processing nonconforming monitoring or measuring resources</li> <li>Qualifying calibration labs (external providers)</li> <li>Computer software used for verification of products and for monitoring manufacturing processes is validated</li> </ul>
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<b>MEASUREMENT AND IMPROVEMENT PROCESSES (MIPs)</b>
-----------------------------------------------------

<b>Control of Nonconforming Outputs</b>
-----------------------------------------

<b>Purpose</b>	To identify, control and disposition nonconforming outputs (products and services).
<b>Process Owners</b>	Quality / Engineering
<b>Sub-Processes and Procedures</b>	<ul style="list-style-type: none"> <li>Identifying, documenting and segregating (where applicable) nonconforming products and services</li> <li>Making nonconforming products and services disposition decisions</li> <li>Reworking and verifying nonconforming products and services</li> </ul>

<b>Internal Audits</b>
------------------------

<b>Purpose</b>	To verify conformity of the quality management system.
<b>Process Owner</b>	Quality
<b>Sub-Processes and Procedures</b>	<ul style="list-style-type: none"> <li>Scheduling of internal audits.</li> <li>Conducting internal audits of the quality management system.</li> <li>Monitoring the effectiveness and efficiency of the internal audits.</li> <li>Conducting training of internal auditors.</li> </ul>

<b>Nonconformities, Corrective Actions, Risk and Opportunity</b>
------------------------------------------------------------------

<b>Purpose</b>	To request, implement and follow up nonconformities, corrective actions, risk and opportunity.
<b>Process Owner</b>	Quality
<b>Sub-Processes and Procedures</b>	<ul style="list-style-type: none"> <li>Evaluating the need for corrective actions, risk and opportunity</li> <li>Requesting and implementing corrective actions, risk and opportunity</li> <li>Verifying the implementation and effectiveness of corrective actions, risk and opportunity</li> </ul>

<b>Customer Complaints &amp; Satisfaction</b>
-----------------------------------------------

<b>Purpose</b>	To process customer feedback and complaints and to measure customer satisfaction.
<b>Process Owner</b>	Customer Service
<b>Sub-Processes and Procedures</b>	<ul style="list-style-type: none"> <li>Receiving and logging customer feedback and complaints</li> <li>Processing and responding to customer complaints</li> <li>Gathering of information and data about customer satisfaction</li> <li>Analyzing, reporting and presenting customer satisfaction information and data (preparing reports, plotting charts, holding meetings, etc)</li> </ul>

	<b>QUALITY MANAGEMENT SYSTEM</b>			
	Quality System Manual	Section 4	Rev.: G	Pg. 20 of 52

<b>MANAGEMENT RESPONSIBILITY PROCESSES (MRPs)</b>	
<b>Planning and Objectives</b>	
<b>Purpose</b>	To define the quality policy and quality objectives, to plan the quality management system (QMS), and to implement management commitments.
<b>Process Owner</b>	Management
<b>Sub-Processes and Procedures</b>	<ul style="list-style-type: none"> <li>• Establishing quality policy</li> <li>• Establishing and monitoring of quality objectives</li> <li>• Planning the quality management system</li> <li>• Defining responsibilities and authorities</li> <li>• Appointing Management Representative</li> </ul>
<b>Management Review</b>	
<b>Purpose</b>	To review the suitability and effectiveness of the quality system; to consider changes to the quality system, quality policy and quality objectives; and to identify opportunities for improvement.
<b>Process Owner</b>	Management
<b>Sub-Processes and Procedures</b>	<ul style="list-style-type: none"> <li>• Presentation, discussion and evaluation of review input information</li> <li>• Determining changes required (if any) for the quality policy, quality objectives and the quality management system</li> <li>• Identifying opportunities for improvement and establishing quality objectives</li> </ul>
<b>Improvement</b>	
<b>Purpose</b>	To continually improve the quality management system, processes, products and services.
<b>Process Owner</b>	Management
<b>Sub-Processes and Procedures</b>	<ul style="list-style-type: none"> <li>• Monitoring performance of the quality management system</li> <li>• Requesting and implementing corrective actions, risks and opportunities</li> <li>• Establishing, reviewing and updating the quality policy</li> <li>• Establishing, implementing and monitoring quality objectives</li> <li>• Improving the Quality Management System</li> </ul>
<b>RESOURCE MANAGEMENT PROCESSES (RMPs)</b>	
<b>Personnel Competence and Awareness</b>	
<b>Purpose</b>	To define competency requirements, provide training, and ensure awareness about quality-related issues.
<b>Process Owner</b>	Operations / Quality
<b>Sub-Processes and Procedures</b>	<ul style="list-style-type: none"> <li>• Determining competency requirements for jobs/positions affecting products and services quality</li> <li>• Providing training and/or taking other actions to satisfy competency requirements</li> <li>• Evaluating the effectiveness of training</li> <li>• Providing awareness programs to ensure employee motivation, empowerment, and knowledge of quality-related issues</li> </ul>
<b>Information, Document Control and IT</b>	
<b>Purpose</b>	To control documented information related to products and services, manufacturing processes and the quality system; and to control quality documented information.
<b>Process Owner</b>	Tech Comm
<b>Sub-Processes and Procedures</b>	<ul style="list-style-type: none"> <li>• Establishing documented information needed by the organization</li> <li>• Reviewing and approving documented information</li> </ul>

	QUALITY MANAGEMENT SYSTEM			
	Quality System Manual	Section 4	Rev.: G	Pg. 21 of 52

	<ul style="list-style-type: none"> <li>• Controlling document revisions and distribution (availability)</li> <li>• Managing retention, storage (electronic), and disposition of documented information</li> </ul>
<b>Facilities, Equipment and Work Environment</b>	
<b>Purpose</b>	To ensure appropriate and adequate facilities, production equipment and supporting services.
<b>Process Owner</b>	Operations
<b>Sub-Processes and Procedures</b>	<ul style="list-style-type: none"> <li>• Plant, facility and equipment planning</li> <li>• Maintaining plant, facilities and manufacturing process equipment</li> </ul>



## Quality System Manual - Section 5

### LEADERSHIP

Issued by: Quality Assurance

Eff. Date: 3/11/2020

Rev.: G

Pg. 22 of 52

#### 5.1 Leadership and Commitment

5.1.1 **LND, Inc.** top management shall demonstrate leadership and commitment with respect to the quality management system (QMS) by:

- taking accountability for the effectiveness of the QMS,
- ensuring that the **LND** Quality Policy (1-911-0098) and quality objectives are established for the QMS and are compatible with the context and strategic direction of **LND**,
- ensuring the integration of the QMS into **LND**'s business processes,  
**NOTE:** "Business" can be interpreted broadly to mean those activities that are core to the purpose of LND's existence.
- promoting the use of the process approach and risk-based thinking,
- ensuring that the resources needed for the QMS are available,
- communicating the importance of effective quality management and of conforming to the QMS requirements,
- ensuring that the QMS achieves its intended results,
- engaging, directing and supporting persons to contribute to the effectiveness of the QMS,
- promoting improvement, and
- supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

#### 5.1.2 Customer Focus

The principal objective of the quality management system is to focus our organization on the customer, and in particular, on enhancing customer satisfaction. The key to achieving high customer satisfaction is an accurate determination of customer requirements and an effective verification that the requirements are met.

Top management ensures that customer requirements and risks are determined and are well understood. This is done through the process of order and contract review, as defined in this manual in **QM Section 8.2.1 Determining the Requirements for Products and Services** and **QM Section 8.2.3 Review of Requirements for Products and Services**, and in associated operational procedures.

Approved by/date:

Spencer B Neyland

5 May 2020

Management ensures that customer requirements are met by inspecting and testing products at various stages of production and upon completion, as defined in this manual in ***QM Section 8.6.1 Monitoring and Measurement of Products and Services***, and in associated operational procedures.

Management ensures that customer satisfaction is systematically monitored as a measure of performance in determining and meeting customer requirements. This process is defined in this manual in ***QM Section 9.1.2 Customer Satisfaction***, and in the associated operational procedure.

## 5.2 Quality Policy

### 5.2.1 Establishing the quality policy

Quality policy is established by top management. In formulating the quality policy, top management ensures that the policy is appropriate to the purpose **and content** of the company **and its strategic direction**. It also **satisfies applicable requirements**, and includes a commitment to comply with the requirements and continually improve the effectiveness of the quality management system. Refer to LND procedure ***1-911-0098, LND Quality Policy***.

Quality policy provides a framework for establishing specific quality objectives, and provides direction for the continual improvement effort **of the QMS**. The use of the quality policy in setting quality objectives is addressed in this manual in ***QM Section 6.2 Quality Objectives and planning to achieve them***.

### 5.2.2 Communicating the quality policy

Senior management at ***LND, Inc.*** is responsible for assuring that the quality policy is understood, implemented, and maintained at all levels. Quality policy is posted throughout the company, and its role is explained and discussed at the general orientation training provided to all new employees and/or group training. The quality policy is also communicated to customers, consumers and other interested parties. For this purpose, it is displayed in the reception area and posted on the company's internet site at [www.LNDINC.com](http://www.LNDINC.com).

Quality policy is periodically reviewed within the framework of management reviews of the quality system. This is to ensure its continual relevance and suitability.

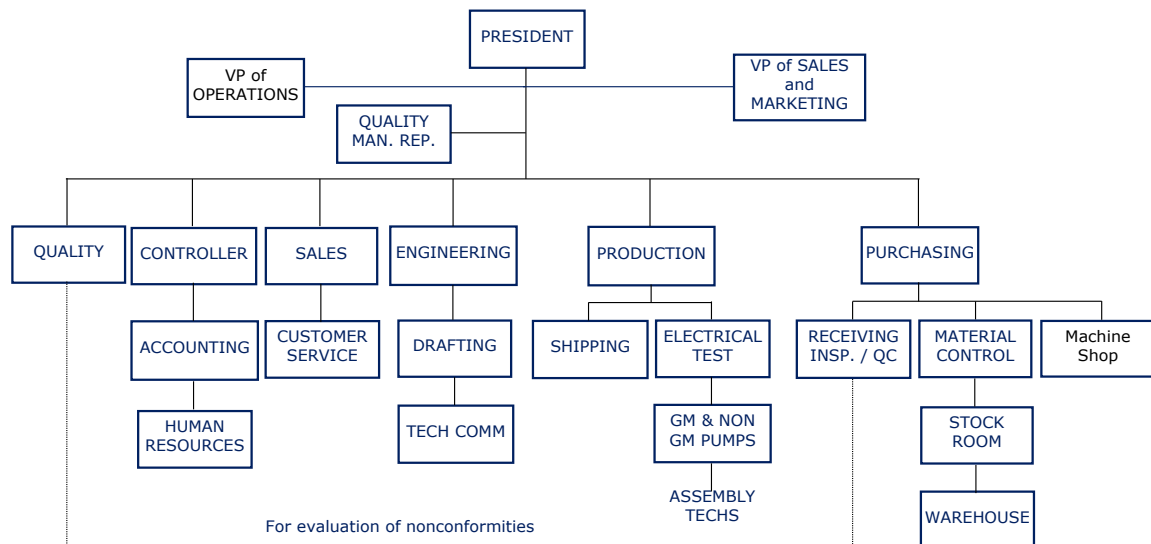
## 5.3 Organizational roles, responsibilities and authorities

***LND, Inc.*** defines the responsibilities and authorities **for relevant roles** at all levels through the Organizational Chart. Interrelation of all personnel who manage, perform and verify work affecting quality is identified in the ***Organizational Chart*** enclosed at

the end of *QM Section 5, Para. 5.3.*

Top management assigns the responsibility and authority (refer to Section 5.3.1, Management Representative) for:

- ensuring that the quality management system conforms to the requirements of ISO9001:2015;
- ensuring that the processes are delivering their intended outputs;
- reporting on the performance of the quality management system and on opportunities for improvement (see Section 10.1 of the this manual), in particular to top management;
- ensuring the promotion of customer focus throughout **LND**; and
- ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.




LND, INC. ORGANIZATIONAL CHART

## 5.3.1 Management Representative

While not required in the current ISO9001 standard, **LND, Inc.** top management has appointed the Vice President of Operations as the Management Representative for the quality management system (QMS). The Management Representative has sufficient independence and authority to ensure nuclear safety related activities are performed to requirements and the QMS requirements are maintained.



	<b>Quality System Manual - Section 6</b>			
	<b>PLANNING</b>			
	Issued by: <b>Quality Assurance</b>	Eff. Date: <b>3/11/2020</b>	Rev.: <b>H</b>	Pg. <b>25</b> of <b>52</b>

## 6.1 Actions to address risks and opportunities

The Quality Management System of **LND, Inc.** analyzes risks associated with programs and activities and looks for opportunities for improvement per Operational Procedure ***QOP 61-01, Risk and Opportunities***.

The purpose of this program is to:

- Give assurance that the Quality Management System can achieve its intended results.
- Enhance desirable effects.
- Prevent, or reduce, undesired effects.
- Achieve improvement.

**6.1.1** An assessment is prepared of the impact new products, projects, or contracts will have with regards to the following resources:

- Information Technology: determine the computer hardware, software, and applications.
- Documentation: Engineering drawings, technical specifications, assembly and test procedures, and other manufacturing documents.
- Equipment: manufacturing equipment, servicing equipment, inspection, measuring and test equipment.
- Human resources: ensure all staff has appropriate skills for the job/tasks performed.
- Parts: availability of raw materials, components, and manufacturing fixtures.
- Quality audits: planned audit(s) after activity completion.

**6.1.2** LND plans actions to address risk and opportunities, and how to:

- integrate and implement the actions into the quality management system processes (see Clauses 4.4), and;
- evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

<b>Approved by/date:</b>	
Spencer B Neyland	5 May 2020

**Note:** Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.


**Note:** Opportunities can lead to the adoption of new practice, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address LND's or customer needs.

## 6.2 Quality Objectives and planning to achieve them

- 6.2.1** When a new product, project, or contract is evaluated for adoption into the **LND, Inc.** quality system, the appropriate staff members of the Design Review Board meet to define and document how the requirements for quality will be met per LND procedures **1-900-0010 (Design Control Flowchart)**, **1-900-0007 (Engineering Changes)**, **1-900-0008 (Customer Order Flowchart)**, and **QOP 74-03 (Verification of Purchased Products and Services)**.
- 6.2.2** Top management ensures that quality objectives are established throughout the organization to implement the quality policy, to meet requirements for products and services, processes, and to improve the quality system and quality performance. Quality objectives are measurable, and reviewed against performance goals at each management review meeting.

## 6.3 Planning of changes

- 6.3.1** When the Management Review members determine that there is a need for change to the **LND, Inc.** Quality Management System, top management shall ensure that changes are planned and implemented to meet the company's quality objectives and the requirements of **QM Section 4.1 Understanding the Organization and its Context**, and the integrity of the quality management system are maintained when changes to the QMS are planned and implemented. Issues considered by the Management Review members are:
- The purpose of the changes and their potential consequences.
  - The integrity of the Quality Management System.
  - The availability of resources.
  - The allocation or reallocation of responsibilities and authorities.
- 6.3.2** The standard does not require retained information (records) of having planned and managed changes, but it would be almost impossible to provide evidence of performing change management without records of some sort.

	<b>Quality System Manual - Section 7</b>			
	<b>SUPPORT</b>			
	Issued by: <b>Quality Assurance</b>	Eff. Date: <b>3/11/2020</b>	Rev.: <b>F</b>	Pg. <b>27</b> of <b>52</b>

## 7.1 RESOURCES

7.1.1 **General** - *LND, Inc.* determines and provides the resources needed to implement and maintain the Quality Management System per Operational Procedure *QOP 56-01, Management Review*. This implementation is achieved with top management commitment and with sufficient resources for the implementation to effectively maintain and continually improve the system, and enhance customer satisfaction.

7.1.2 **People** - During the Management Review process, *LND, Inc.* reviews the human resource requirements to maintain the effective management of the Quality Management System **and for the operation and control of processes.**

7.1.3 **Infrastructure** - *LND, Inc.* provides and maintains buildings, workspace, equipment, and support services needed to achieve conformity to product **and service** requirements. Department managers are responsible for identifying the need and requirements for new, and/or modification or repair of existing infrastructure and facilities in their departments. Requests for changes and/or expansions of facilities are submitted to the Vice President of Operations and then to the President for review and approval.

Normal maintenance of buildings and facilities is performed by *LND, Inc.* personnel assigned to facility and maintenance departments. This includes regularly scheduled maintenance of lighting systems, air conditioning and heating systems, and cleaning. The routine maintenance of LND production and test equipment is as per Operational Procedure *QOP 63-01, Equipment Maintenance*. Extensive repairs of buildings and other such facilities are contracted as needed. Purchasing is responsible for coordinating and managing maintenance contracts.

**Process equipment** - Procurement of new, and/or modification of existing process equipment (both hardware and software) are planned in conjunction with development of manufacturing processes.

**Supporting services** - Supporting services required by *LND, Inc.* include transportation, hazardous waste removal, communication, and some IT services:

- Transportation services are purchased from parcel delivery and courier services, and from trucking or other transportation companies or consolidators, as required. Transportation and hazardous waste removal services are purchased in accordance with Operational Procedure *QOP-74-01 External Provider Evaluation and Monitoring*, and *1-901-0005, LND Supplier Manual*.

<b>Approved by/date:</b>	
Spencer B Neyland	5 May 2020

- Communication services are provided by various telephone, wireless, and internet access companies. Purchasing is responsible for administrating and coordinating these contracts.
- IT systems are designed and implemented by external consultants. These services are purchased in accordance with Operational Procedure ***QOP-74-01 External Provider Evaluation and Monitoring***, and ***1-901-0005, LND Supplier Manual***. Normal day-to-day operations of the LND IT systems (AS400, PICS intranet, and internet) are controlled and maintained by the IT department.

**7.1.4 Environment for the operation of processes** - Operations and departmental managers are responsible for ensuring suitable social and psychological conditions in the workplace. This is to include such aspects as interaction and communication between employees, employee harassment, conflict resolution, and so forth. Relevant workplace policies are implemented mainly through training and awareness programs and, where necessary, disciplinary actions.

Production, Operations and Quality are responsible for identifying those operations where extreme environmental conditions could impact quality performance of personnel and result in products and services nonconformities. Where appropriate, limits of exposure and/or mitigating measures shall be defined and implemented for these operations.

Health and safety management system is independent from the quality management system. It is administrated by Operations and is documented in the **LND Safety Program Manual (LND 1-915-0069)**.

#### **7.1.5 Monitoring and measuring resources**

**7.1.5.1** ***LND, Inc.*** has determined and provided the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirement. The procedure, ***QOP 76-01, Measuring and Monitoring Resources***, outlines the process used to ensure that monitoring and measurements to be complied with are carried out in a manner that is consistent with our monitoring and measuring requirements.

LND ensures that the resources provided:

- are suitable for the specific type of monitoring and measurement activities being undertaken; and
- are maintained to ensure their continuing fitness for their purpose.

LND retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

**7.1.5.2** When measurement traceability is a requirement, or is considered by

***LND, Inc.*** to be an essential part of providing confidence in the validity of measurement results, measuring equipment is:

- calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no standard exists, the basis used for calibration or verification shall be retained as **documented information**,
- identified in order to determine their status; and
- safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

***LND, Inc.*** determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and takes appropriate action as necessary.

**7.1.5.3** Quality Assurance assesses and documents the validity of the previous measuring results when the equipment is found not to conform to requirements. ***LND, Inc.*** takes appropriate action on the equipment and any products and services affected. Documented information of the results of calibration and verification are maintained.

**7.1.6 Organizational Knowledge** – ***LND, Inc.*** has determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services, **and has made that knowledge available as necessary**. Technical and manufacturing knowledge is recorded and documented in accordance with Operational Procedure ***QOP 42-01, Control of Documents***.

Organizational knowledge based on internal sources (e.g. intellectual property, inventions, new research, etc...) is the property of ***LND, Inc.***

Organizational knowledge based on external sources (e.g. industry standards, academia, contractors, etc...) is gathered, stored and reviewed by the responsible departments. Industry manufacturing standards that impact LND are the responsibility of Engineering. Quality standards that impact that impact LND are the responsibility of the Quality Assurance Manager. Safety and environmental standards that impact LND are the responsibility of the Vice President of Operations.

Organizational knowledge discussions and changes appear in Topic 7, 'Changes in internal and external issues' of the LND Management Review Report (1-911-0055).

## 7.2 Competence

- 7.2.1** Personnel performing work affecting conformity to products and services requirements are competent. Competency is determined on the basis of appropriate education, training, skills and experience. Conformity to products and services requirements may be affected by personnel who are directly or indirectly responsible for tasks within the quality management system.
- 7.2.2** Responsibilities and Authority – The Vice President of Operations is responsible for establishing and maintaining policy and procedures for identifying training needs. Department managers and leadpersons are responsible for identifying competency requirements and for providing training in their areas. Competency training is primarily focused on increasing the level of skills in operating equipment and processes, conducting inspections and testing, computerized data entry, and other such skills as appropriate for particular positions and jobs.
- The Quality Assurance Manager is responsible for reviewing training needs and maintaining training records as defined under record retention Operational Procedure ***QOP42-02, Control of Documented Information***.
- 7.2.3** Quality Activity - The objective of the company's training program is to ensure that employees possess the required knowledge and skills for performing their jobs **and performing those jobs safely**; and that they are familiar with relevant requirements of the quality system pertaining to their job functions. Refer to Operational Procedure ***QOP 62-01, Competence, Awareness and Training***.

## 7.3 Awareness

- 7.3.1** LND, Inc. determines the necessary competence for personnel performing work-affecting quality. These competencies are translated into essential job duties and described in job descriptions. LND, Inc. communicates to its employees the importance of customer requirements, and the relevance of individual contributions towards meeting these requirements and achieving the quality policy and objectives during informal and scheduled training classes and meetings.
- 7.3.2** Processes for ensuring adequate competency and awareness of personnel are defined in Operational Procedure ***QOP-62-01 Competence, Awareness and Training***. The procedure addresses issues related to:
- Determining competency requirements,
  - Identifying training needs,
  - Providing training,
  - Evaluating the effectiveness of training,
  - Ensuring quality awareness, and
  - Maintaining training documented information.

## 7.4 Communication

**7.4.1** Internal Communication – Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS include weekly department leadperson meetings and daily (management) production meetings, internal audit closing meetings, **manufacturing alerts**, and other routine business communication. **LND, Inc.** communicates the effectiveness of its quality management system periodically to staff via Management Review meetings per Operational Procedure ***QOP 56-01, Management Review***.

The primary method of basic communication is via telephones, email or faxes. Responsibility for the setup, maintenance and servicing of this activity is with the Vice President of Operations. Email accounts are established for all applicable employees. Limitations are established by the IT department to prevent unauthorized communication. Security of the electronic communications system is handled by the IT department.

The communication of new or revised controlled documents is conducted per Operational Procedure ***QOP 42-01, Control of Documents***.

## 7.5 Documented information

**7.5.1 General** - The **LND, Inc.** Quality Management System contains documented information this is required by ISO 9001 and information determined to be necessary for the effectiveness of the LND Quality Management System. See section 4.3.2 for the breakdown on document structure. **Documented information encompasses both documents and records. Documents are living information that is used for decision making or performing tasks (i.e.; procedures, policies, blank checklists). Records contain historical information about things that already happened.**

### 7.5.2 Creating and updating

**7.5.2.1** Control of Documents - **LND, Inc.** is transitioning from paper to electronic documentation. As this transition progresses, new categories of documents are transferred from paper to electronic document control system. Both systems are currently used, and are defined in Operational Procedure ***QOP-42-01 Control of Documents***.

**LND, Inc.** quality system documentation comprises the following categories:

- A documented Quality Policy and quality objectives;
- Quality Manual;
- Quality system operational procedures and documented information;



- Quality system forms;
- Work instructions;
- Product labeling and packaging specifications;
- Manufacturing specifications;
- Quality assurance/control procedures, documented information and specifications;
- Standards and codes;
- Government specifications and standards; and
- Regulatory specifications and standards.

These categories are further defined in Operational Procedure ***QOP-42-01 Control of Documents***.

The document control system defined in Operational Procedure ***QOP-42-01 Control of Documents*** ensures that:

- Documents are reviewed for adequacy and are approved prior to release;
- Documents are reviewed and updated as necessary, and revised documents are re-approved;
- Documents are identified, to include their current revision status and changes;
- Documents are distributed to, and are available at locations where they are used;
- Documents remain legible and readily identifiable;
- Document of external origin determined by ***LND, Inc.*** to be necessary for the planning and operation of the QMS are identified and their distribution controlled; and
- Obsolete documents are withdrawn from points of use, and/or are clearly identified to prevent their unintended use.

**7.5.3 Control of documented information** - Documented information is established and controlled providing evidence of conformity to requirements and of the effective operation of the quality management system. Operational Procedure ***QOP-42-02 Control of Documented Information*** defines specifically what documented information is maintained in each category and designates their storage locations, retention periods and disposal. It also defines the process for ensuring that documented information is legible, readily identified, has been stored in appropriate locations and conditions, are adequately protected, and are easily retrievable.


The following are examples of ***LND, Inc.*** quality records:

- Organizational Charts (section 5.3)



- Management Review Meeting Minutes
- Approved Supplier Listing
- Production Test Records
- Non-Conformance Records
- Process/Product Validation Reports
- Equipment Calibration Records
- Complaint Records
- Part 21 Records
- Internal Audit Records
- Training Records

Customers are permitted access to quality records where provision is made in approved contracts.

	<b>Quality System Manual - Section 8</b>			
	<b>OPERATIONS</b>			
	Issued by: <b>Quality Assurance</b>	Eff. Date: <b>3/11/2020</b>	Rev.: <b>G</b>	Pg. <b>34</b> of <b>52</b>

## 8.1 Operational planning and control

**8.1.1** Quality planning and control is all about how LND establishes, resources, and manages the production process which includes products and services. Planning is required before new products and services, or processes are implemented. The planning includes the determination of:

- Requirements and quality objectives for products and services, and processes;
- The need to develop production processes and documents; establish process specifications, operator instructions and other such documentation; and provide training to process operators;
- Required product verification, validation, monitoring, measurement, inspection and test activities, and the criteria for products and services acceptance;
- Documented information needed to provide evidence that the realization process and resulting products and services, and processes meet requirements: and
- Determining the resources needed to achieve conformity to the products and services requirement.

Results of production and quality planning are documented on the AS400 computer system, and in the form of dated and signed drawings/work instructions.

**8.1.2** LND controls planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. LND also ensures that outsourced processes are controlled as stated in Section 8.4 of this manual.

## 8.2 Requirements for products and services

### 8.2.1 Customer communication

**8.2.1.1** Arrangements for communicating with customers regarding customer views and perceptions, and complaints are defined in Operational Procedures ***QOP-82-01 Customer Satisfaction*** and ***QOP-85-02 Customer Complaints***. On a regular basis complaint trend analysis reports are prepared and submitted to management for management review meetings

***LND, Inc.*** has implemented an effective procedure for communicating with customers in relation to:

<b>Approved by/date:</b>	
Spencer B Neyland	5 May 2020

- Products and services information (i.e.; service agreements, data sheets, website, product samples),
- Handling enquiries, contracts or orders, including amendments,
- Customer feedback (views and perception), including customer complaints,
- Handling or controlling customer property (refer to LND procedure *1-911-0036, Control of Property Not Owned By LND, Inc.*), and
- Establishing specific requirements for contingency actions (i.e., lost or late shipment, product failure in the field, weather emergencies, labor stoppages, etc.), when relevant.

**8.2.1.2** Arrangements for communicating with customers regarding enquiries and order handling are defined in flowchart LND Procedure *1-900-0008, Customer Order*.

## **8.2.2 Determining the requirements for products and services**

**8.2.2.1** For product and service requirements specified by the customer (special orders), various *LND, Inc.* departments (Sales, Engineering, Production, QA) review the requirements. The requirements not specified by the customer are also reviewed, and the company's capacity and capability to meet all applicable requirements are determined before the order is taken. This process is defined in LND procedure *1-900-0010, Design Control Flowchart*.

**8.2.2.2** For product and service requirements not specified by the customer (catalog products), *LND, Inc.* requirements for product characteristics, packaging, and support are determined and reviewed in the process of designing and developing the product per LND procedures *1-900-0008, Customer Order Flowchart* and *1-900-0010, Design Control Flowchart*.

## **8.2.3 Review of the requirements for products and services**

**8.2.3.1** Prior to the commitment to supply products and services to the customer, orders are reviewed to include:

- Requirements specified by the customer, including the requirements for delivery and post-delivery activities are defined;
- Requirements not specified by the customer, but necessary or the specific or intended use, when known;
- Requirements specified by the organization;

- Statutory and regulatory requirements applicable to the products and services;
- Contract or order requirements differing from those previously expressed are resolved; and
- When the customer provides no documented statement of requirements (as with verbal orders), the customer requirements are confirmed before acceptance.

**8.2.3.2** Documented information of the results of the review and any new requirements are maintained. Refer to ***QM Section 7.5.3, Control of Documented Information.***

#### **8.2.4 Changes to requirements for products and services**

Change orders and amendments are processed and reviewed using the same procedures that apply to the processing of initial orders. Change orders are communicated to all functions within the company that may be affected by the change of customer requirements. When a formal review is deemed impractical for orders, such as internet sales, the review shall cover relevant product information such as catalogs or advertising material.

### **8.3 Design and development of products and services**

**8.3.1 General** – ***LND, Inc.*** has established, implemented, and maintains a design and development process to ensure the subsequent provision of our products and services.

**8.3.1.1** ***LND, Inc.*** controls and verifies the design of the product in order to ensure specified requirements are met per LND procedure ***1-900-0010, Design Control Flowchart.***

**8.3.1.2** ***LND, Inc.*** controls and verifies the design and development activities, including defined responsibilities. Only LND staff or personnel with adequate resources are assigned design and development activities.

**8.3.1.3** For customer orders the customer specification is the design input and the Design Review Specification Sheet (LND Form 1-900-0017), prepared in response to customer specification, become the design output.

**8.3.1.4** Design changes follow the same review process as initial designs.

#### **8.3.2 Design and development planning**

**8.3.2.1** ***LND, Inc.*** designs its own standard catalog products as well as customer-specified products and services, and modifications. Engineering is responsible for design. The quality system for design and development is defined in LND Procedure ***1-900-0010, Design Control Flowchart.***

**8.3.2.2** Engineering is responsible for the planning of design projects, including the identification of design, review, verification and validation activities; scheduling the project; assignment of qualified personnel; and control of organizational and technical interfaces.

### **8.3.3 Design and development inputs**

Design input requirements are developed by Engineering from product concepts, such as products and services briefs, sketches, models, rough prototypes, etc. Design inputs are reviewed and approved before they are used in design. Inputs shall include;

- Functional and performance requirements,
- Information derived from previous similar designs (when applicable),
- Statutory and regulatory requirements,
- Standards or codes of practice that the organization has committed to implement,
- Potential consequences of failure due to the nature of the products and services.

**8.3.3.1** Design inputs are reviewed for adequacy. Requirements are complete, well defined and do not conflict with each other.

**8.3.3.2** Documented information is maintained in accordance with *QM Section 7.5.3, Control of Documented Information*.

### **8.3.4 Design and development controls**

**8.3.4.1** *LND, Inc.* conducts formal documented reviews of design results at appropriate intervals. **Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination.**

**8.3.4.2** *LND, Inc.* performs design verification to ensure that the design output meets the design input requirements at appropriate stages of design and to ensure that design verification measures are documented.

**8.3.4.3** *LND, Inc.* performs design validation to ensure that the product conforms to defined customer requirements.

**8.3.4.4** Documented information is maintained and retained in accordance with *QM Section 7.5.3, Control of Documented Information*.

### **8.3.5 Design and development outputs**

Design and development outputs are documented, checked and verified

against design and development inputs, and **are adequate** before they are released for production. Design and development outputs;

- Meet the design and development input requirements,
- **Include or reference monitoring and measuring requirements, as appropriate, and** Contain or reference product acceptance criteria,
- Specify the characteristics of the product **and services** that are essential for **their intended purpose and their** safe and proper **provision**, and
- Review of design output documents before release.

**8.3.5.1** Documented information on design and development outputs shall be retained in accordance with ***QM Section 7.5.3, Control of Documented Information.***

### **8.3.6 Design and development changes**

**8.3.6.1** Design and development changes are initiated, processed and controlled using the Engineering Change Request (ECR) system defined in LND Procedure ***1-900-0007, Engineering Changes.*** Design changes are reviewed, verified and validated as appropriate, **and actions are taken to prevent adverse impacts** before **approval and** implementation.

**8.3.6.2** Review of design and development changes include an evaluation of the change on constituent parts and products and services already delivered.

**8.3.6.3** Documented information of the results of review of changes, and any necessary actions, are maintained in accordance with ***QM Section 7.5.3, Control of Documented Information.***

#### 8.4 Control of externally provided processes, products and services

**8.4.1 General** – *LND, Inc.* has procedures in place to ensure that externally provided processes, products, and services conform to established requirements.

Operational Procedure ***QOP 74-03 Verification of Purchased Products and Services*** is followed to ensure that purchased products and services conform to the specified purchase requirements.

*LND determines and applies the criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. Refer to Operational Procedure ***QOP 74-01, External Provider Evaluation and Monitoring***.*

*Evidence of conformity with the acceptance criteria is maintained. Refer to Operational Procedure ***QOP 42-02, Control of Documented Information***.*

#### 8.4.2 Type and extent of control

*LND ensures that externally provided processes, products and services do not adversely affect the ability of LND to consistently deliver conforming products and services to our customers.*

**8.4.2.1** Purchasing documents clearly and completely describe the ordered products and services, including;

- Requirements for approval of products and services, procedures, processes and equipment,
- Requirements for qualification of personnel, and
- Quality management system requirements.

**8.4.2.2** *LND, Inc.* has developed a ***Supplier Manual (1-901-0005)*** that outlines the extent of control and responsibilities required by the external providers. *The Suppliers Manual is available for download on the LND website ([www.LNDINC.com](http://www.LNDINC.com)). Also, copies of the manual are available by contacting the LND Quality Assurance Manager.*

**8.4.2.3** Purchasing documents are reviewed for adequacy of requirements and approved prior to orders being placed with external providers.

**8.4.2.4** Purchased products and services are verified prior to use in production and/or dispatch to customers. Engineering and Quality are responsible for selecting appropriate methods for purchased product verification and acceptance. Operational Procedure ***QOP-74-03 Verification of Purchased Products and Services*** defines the processes for verifying, identifying and releasing purchased

products and services.

### 8.4.3 Information for external providers

**8.4.3.1** *LND, Inc.* purchasing documents describe the materials or services ordered, and the requirements for approval of materials and/or services. LND documents the review and approval of purchase records prior to release per Operational Procedure ***QOP-74-03 Verification of Purchased Products and Services***. Personnel performing this important quality activity are trained and documented as per Operational Procedure ***QOP 62-01, Competence, Awareness and Training***.

**8.4.3.2** Any records of interactions between external providers and LND shall be maintained via emails, printed documents, and handwritten notes. These records shall be maintained (as appropriate) by the department (Supply, Quality, QC/Receiving) interacting with the external provider.

**8.4.3.3** Verification that purchased material meet specified purchase requirements is performed per Operational Procedure ***QOP-74-03 Verification of Purchased Products and Services***. All incoming inspection records are kept on computer files in the Receiving/QC department under the control of the QC inspector.

**8.4.3.4** If verification of purchased product is ever performed at the external provider's facility by representatives from LND or its customers, the LND purchasing documents specify the intended verification arrangements and method of product release.

## 8.5 Production and service provision

**8.5.1 Control of production and service provision** - Product manufacturing is carried out under controlled conditions. The controlled conditions shall include, as applicable:

- The availability of documented information that defines the characteristics of the products to be produced, the services to be provided, or the activities to be performed, and the results to be achieved,
- The availability of work instructions (PICS system procedures),
- Production processes and equipment are properly monitored and controlled,
- Production processes and equipment are properly approved and validated,
- The availability and use of suitable monitoring and measuring resources,
- The implementation of monitoring and measurement activities at



appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met,

- The use of suitable infrastructure and environment for the operation of the processes,
- The appointment of competent persons, including any required qualification,
- The implementation of actions to prevent human error, and
- The implementation of release, delivery and post-delivery activities.

**8.5.1.1** *LND, Inc.* validates any special processes where the resulting output cannot be verified by subsequent measurement or monitoring. This includes any processes where deficiencies become apparent only after the product is in use. Validation demonstrates the ability of these processes to achieve planned results. The process for validation includes;

- Defined criteria for review and approval of the processes,
- Approval of equipment,
- Qualification of personnel,
- Use of specific methods and procedures,
- Requirement for documented information, and
- Revalidation.

## **8.5.2 Identification and traceability**

**8.5.2.1 Identification** - Materials, components, finished products, including inspection and test status are identified throughout all stages of product realization and when in storage. The system and methods for identifying products and services are explained in Operational Procedure ***QOP-74-03 Verification of Purchased Products and Services*** and ***QOP-75-05 Storage, Handling and Preservation***.

*LND, Inc.* shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

**8.5.2.2 Traceability** - Traceability is maintained when required by applicable laws and regulations, or when specified internally to facilitate corrective actions. Traceability is based on identifying the finished products and services, or batches, with unique control numbers. Activities related to maintaining and recording traceability are addressed in Operational Procedures ***QOP-74-03***

***Verification of Purchase Products and Services.***

**LND, Inc.** shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

- 8.5.2.3 Product status** - Throughout products and services realization, and when in storage, products and services are identified with respect to their status, e.g., to indicate whether they have passed or failed the specified inspections and/or tests. This is to prevent nonconforming product from being used or dispatched. General requirements for status identification are defined in Operational Procedure ***QOP-74-03 Verification of Purchased Products and Services.***

**LND, Inc.** shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

**8.5.3 Property belonging to customers or external providers**

- 8.5.3.1** The company exercises care with customer and external provider property while it is under the organization's control or being used. LND Procedure ***1-911-0036, Control of Property Not Owned By LND Inc.***, outlines the identification, verification, protection and safeguarding of customer and external provider property. If any customer or external provider property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and documented information maintained.

- 8.5.3.2** Property belonging to a customer or external provider can include materials, components, tools and equipment, intellectual property and personal data.

**8.5.4 Preservation**

- 8.5.4.1** Departments and functions manufacturing, transporting, storing or otherwise handling products are responsible for developing appropriate handling techniques and procedures, and for protecting and preserving the product while in their custody. Preservation also applies to the constituent parts of the product.

- 8.5.4.2** Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection. Operational Procedure ***QOP-75-05 Storage, Handling and Preservation*** define how these policies are implemented.

**8.5.5 Post-delivery activities**

- 8.5.5.1** Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services,

and supplementary services such as recycling or final disposal.

In determining the extent of post-delivery activities that are required, LND considers statutory and regulatory requirements, the potential undesired consequences associated with it's the products and services, the use and intended lifetime of the products and services, customer requirements, and customer feedback.

*LND, Inc.* has procedures in place to meet the requirements for post-delivery activity associated with our products. Refer to LND procedure *1-913-0005, Customer Returns* and Operational Procedure *QOP 82-01, Customer Satisfaction*.

#### 8.5.6 Control of changes

**8.5.6.1** *LND, Inc.* has procedures in place for the control of documents and procedures per Operational Procedure *QOP 42-01, Control of Documents*. Engineering Change Requests indicate the reason for changes per LND procedure *1-900-0007, Engineering Changes*. When policy and quality objectives are formally reviewed as part of the Management Review process, changes are controlled per Operational Procedure *QOP 56-01, Management Review*.

### 8.6 Release of products and services

#### 8.6.1 Monitoring and measurement of product

- 8.6.1.1** *LND, Inc.* monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process identified in the Process Map, Section 4.4 of this manual.
- 8.6.1.2** *LND, Inc.* ensures that incoming parts and components are not used or processed until they have been inspected as per Operational Procedure *QOP 74-03, Verification of Purchased Product*.
- 8.6.1.3** *LND, Inc.* inspects and tests in-process materials, components and parts as appropriate per Operational Procedure *QOP 82-03, In-Process Inspections*.
- 8.6.1.4** Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of product. Refer to Operational Procedure *QOP-42-02, Control of Documented Information*.
- 8.6.1.5** Product release to the customer does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer. Refer to Operational Procedure *QOP-82-04,*

*Final Inspection.*

## 8.7 Control of nonconforming outputs

- 8.7.1** *LND, Inc.* ensures that products and services which do not conform to specified requirements are identified and controlled to prevent its unintended use, installation or delivery. The controls and related responsibilities and authorities for dealing with nonconforming products and services are defined in Operational Procedure ***QOP-83-01 Control of Nonconforming Products and Services***. Documentation of product nonconformance includes identification, evaluation, and of the nonconforming product.
- 8.7.2** *LND, Inc.* deals with nonconforming products and services by one or more of the following ways;
- By taking action to eliminate the detected nonconformity,
  - By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer,
  - By taking action to preclude its original intended use or application, and
  - By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming products and services are detected after delivery or use has started.
  - Should a recall of LND products be necessary, LND procedure ***1-900-0023, Product Recall*** is followed.
- 8.7.3** *LND, Inc.* applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When considering suitable methods, *LND, Inc.* considers the type and extent of monitoring or measurement appropriate to each process in relation to their impact on the conformity of products and services requirements and on the effectiveness of the quality management system.
- 8.7.3.1** When a quality system process does not conform to requirements, Quality initiates a corrective action request to address the problem. The process for requesting and implementing corrective actions is defined in Operational Procedure ***QOP-85-03 Corrective Action***.
- 8.7.4** Documented information of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained in accordance with Operational Procedure ***QOP-42-02, Control of Documented Information***. The identity of the authority deciding the action(s) is documented.
- 8.7.5** When nonconforming products and services are corrected it is subject to re-verification to demonstrate conformity to the planned requirements.

	<b>Quality System Manual - Section 9</b>			
	<b>PERFORMANCE EVALUATION</b>			
	Issued by: <b>Quality Assurance</b>	Eff. Date: <b>09/17/19</b>	Rev.: <b>B</b>	Pg. <b>45</b> of <b>52</b>

## 9.1 Monitoring, measuring, analysis and evaluation

**9.1.1 General - *LND, Inc.*** plans and implements the measurement, analysis and improvement operations to verify whether quality activities comply with planned arrangements and to determine the effectiveness of the quality system;

- To demonstrate conformity to products and services requirements,
- To ensure conformity of the quality management system, and
- To continually improve the effectiveness of the quality management system.

The above listed processes are identified in documented procedures and include determination of applicable methods, and the extent of their use.

*LND, Inc.* monitors and measures the performance and determines the effectiveness of the quality management system per Operational Procedure ***QOP 82-02, Internal Quality Audits***. All audit reports and activities are reviewed by the Management Representative.

**9.1.2 Customer satisfaction – *LND, Inc.*** determines, monitors, and measures customer satisfaction by various methods. The following are some of the methods by which customer satisfaction is determined:

- Both solicited and unsolicited customer satisfaction and feedback.
- Feedback on delivered products and services.
- Awards and recognition.
- Product returns.
- Warranty claims.
- Repeat customers.
- Market share analysis.

**9.1.2.1** Customer satisfaction trend analysis information is reported to, and evaluated by the management review of the quality system, as defined in Operational Procedure ***QOP-56-01 Management Review***.

**9.1.2.2** Operational Procedure ***QOP-82-01 Customer Satisfaction*** defines the responsibilities and methods for collecting the information.

<b>Approved by/date:</b>	
Spencer B. Neyland	17 September 2019

### 9.1.3 Analysis and evaluation

- 9.1.3.1 Data and information recorded in quality documented information are compiled and analyzed periodically to determine trends in the performance and effectiveness of the quality management system and to identify opportunities for improvement.
- 9.1.3.2 The process for determining, collecting and analyzing this data is defined in the Operational Procedure ***QOP-84-01 Analysis of Data***. Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.
- 9.1.3.3 The analysis of data provides information relating to;
- conformity of products and services,
  - the degree of customer satisfaction,
  - the performance and effectiveness of the quality management system,
  - if planning has been implemented effectively,
  - the effectiveness of actions taken to address risk and opportunities,
  - performance of external providers, and
  - the need for improvements to the quality management system.

## 9.2 Internal audit

- 9.2.1 Quality is responsible for coordinating the internal audits of the quality management system at planned intervals to determine whether the quality management system:
- Conforms to the quality management system requirements as defined in the ***LND, Inc.*** quality manual and operational procedures, and to the requirements of the ISO 9001 standard,
  - Is effectively implemented and maintained.

- 9.2.2 Operational Procedure ***QOP-82-02 Internal Quality Audits*** defines the responsibilities and requirements for planning, conducting and reporting internal audits, as well as taking corrective actions and follow-ups.

Internal audits are conducted in accordance with a planned program, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of the previous audits.

Necessary corrections and corrective actions are taken without undue delay by management personnel responsible for the areas where nonconforming processes and/or practices are identified by the audit. Auditors follow up to

ensure that the actions taken are fully implemented and are effective.

Audits are scheduled annually or as required. Audit records and corrective actions are maintained. An annual internal audit plan is prepared by the Q.A. Manager and distributed to all relevant locations and individuals. Qualified internal auditors are assigned areas over which they have no direct responsibility.

The results of the internal audits are shared with the Management Representative and personnel responsible for the area audited. LND takes timely corrective action on the deficiencies found during the internal audit. Follow-up audits, if necessary, record the implementation and effectiveness of the corrective action taken.

Documented information of the audit and its results shall be maintained in accordance with ***QM Section 7.5.3, Control of Documented Information.***

### **9.3 Management review**

**9.3.1** General - Top management reviews the QMS at the management review meetings. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes (including the quality policy and quality objectives). Documented information is maintained for each management review meeting. Refer to Operational Procedure ***QOP-56-01, Management Review.***

#### **9.3.2 Management review inputs**

Input into the management reviews consists of information on the performance and effectiveness of the quality management system. At a minimum, this includes trends in:

- Process performance and conformity of products and service,
- Effectiveness of actions taken to address risk and opportunities,
- Customer satisfaction and feedback/complaints from relevant interested parties,
- Results of audit activities (i.e. customer, internal, supplier, process audits. Promote prompt completion),
- Status of quality objectives (extent to which objectives have been met),
- Safety and environmental issues,
- Status of actions (open items) from previous MRM meetings,
- Opportunities for improvement,
- Nonconformities and corrective actions,
- Changes in external and internal issues that are relevant to the QMS,
- Adequacy of resources,

- New issues,
- Performance of external providers (annual report),
- Monitoring and measurement results,
- Compliance to Quality Policy (annual report).

### 9.3.3 **Management review outputs**


During the review meetings, management will identify decisions and actions to be taken regarding the following issues;

- Any need for changes to the Quality Management System,
- Opportunities for improvement, and
- Resource needs.

Responsibility for required actions is assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of the management review.


Documented information of the management review and its results shall be maintained in accordance with ***QM Section 7.5.3, Control of Documented Information.***



	<b>Quality System Manual - Section 10</b>			
	<b>IMPROVEMENT</b>			
	Issued by: <b>Quality Assurance</b>	Eff. Date: <b>9/17/19</b>	Rev.: <b>C</b>	Pg. <b>49</b> of <b>52</b>

- 10.1 General - *LND, Inc.*** continuously improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, customer survey results, customer complaint forms, analysis of data, corrective actions, risks and opportunities, and management review.
- 10.1.1** *LND, Inc.* encourages personnel at all levels to provide ideas for improving products, processes, systems, productivity, and the work environment.
- 10.1.2** *LND, Inc.* works to improve its products and processes per LND procedure **1-900-0010, Design Control Flowchart**, and always looks to develop new products. When inputs are received from external or internal sources, members of the Design Review Board review the inputs and determine risks.
- 10.1.3** As part of LND's commitment to continuous improvement, preventive actions are discussed at Management Review Meetings to prevent undesired effects.
- 10.2 Nonconformity and corrective action**
- 10.2.1** *LND, Inc.* ensures products or components that do not conform to specified requirements are prevented from unintended use or installation per Operational Procedure ***QOP 83-01 Control of Nonconforming Product***. Documentation of product nonconformance includes identification, evaluation, and disposition of the nonconforming product.
- 10.2.2** Nonconforming products/services are clearly marked and segregated. The procedure for nonconforming production includes determination of the cause, implementation of corrective actions, and dealing with the consequences. These activities and their effectiveness are reviewed and discussed during the management review meetings.
- 10.2.3** *LND, Inc.* may perform the following for nonconforming products or components:
- Rework nonconforming products or components to meet applicable specifications.
  - Conditionally accept nonconforming product (with or without repair) if its suitability is not significantly diminished.
  - Evaluation nonconforming product or components for alternate applications.

<b>Approved by/date:</b>	
Spencer B. Neyland	17 September 2019

	IMPROVEMENT			
	Quality System Manual	Section 10	Rev.: C	Pg. 50 of 52

- Reject or scrap nonconforming products or components.

**10.2.4** *LND, Inc.* reinspects all reworked products and components to ensure they meet established specifications.

**10.2.5** Corrective Action – *LND, Inc.* maintains documented procedures for implementing effective corrective action per Operational Procedure *QOP 85-03, Corrective Action* and *QOP 85-02 Customer Complaints*. Corrective actions shall be appropriate to the effects of the nonconformities encountered. This includes;

- Reviewing and analyzing nonconformities,
- Determining the causes of the nonconformities,
- Determining if similar nonconformities exist, or could potentially occur,
- Implementing any actions needed, including, if appropriate, updating documentation,
- Updating risks and opportunities determined during planning, if necessary,
- Recording the nature of the nonconformities and any subsequent actions taken,
- Reviewing the corrective action taken and its effectiveness,
- Recording the results of any corrective action, and
- Making changes to the quality management system, if necessary.

**10.3** **Continual improvement** – *LND, Inc.* works to continually improve the suitability, adequacy and effectiveness of the Quality Management System, taking into consideration the results of analysis and evaluation, and the outputs from management review. *Refer to QM Section 6.1, Actions to address risk and opportunity; and QM Section 9.1, Monitoring, measuring, analysis and evaluation.*

ISO 9001:2015		ISO 9001:2008	
0.	Introduction	0.	Introduction
1.	Scope	1.	Scope
2.	Normative references	2.	Normative references
3.	Terms and definitions	3.	Terms and definitions
4.	Context of the organization		
4.1	Understanding the organization and its context	1.1	General
4.2	Understanding the needs and expectations of interested parties	4.1	General requirements
4.3	Determining the scope of the quality management system	1.1	General
4.4	Quality management system and its processes	7.2.1	Determination of requirements related to the product
		1.2	Application
		4.2.2	Quality manual
		4.1	General requirements
5.	Leadership	5.	Management responsibility
5.1.1	Leadership and commitment for the quality management system	5.1	Management commitment
5.1.2	Customer focus	5.2	Customer focus
5.2	Quality policy	5.3	Quality policy
5.3	Organizational roles, responsibilities and authorities	5.5.1	Responsibility and authority
		5.5.2	Management representative
6.	Planning for the quality management system		
6.1	Actions to address risks and opportunities	5.4.2	Quality management system planning
		8.5.3	Preventive action
6.2	Quality objectives and planning to achieve them	5.4	Planning
6.2.1	Establish quality objectives	5.4.1	Quality objectives
6.2.2	Planning to achieve quality objectives	5.4.2	Quality management system planning
6.3	Planning of changes	5.4.2	Quality management system planning
7.	Support		
7.1	Resources	6.1	Provision of resources
7.1.1	General	6.2.1	General
7.1.2	People	6.1	Provision of resources
7.1.3	Infrastructure	6.3	Infrastructure
7.1.4	Environment for the operation of processes	6.4	Work environment
7.1.5	Monitoring and measuring resources	7.6	Control of monitoring and measuring equipment
7.1.6	Organizational knowledge	6.2.2	Competence, training, and awareness
7.2	Competence	6.2.2	Competence, training, and awareness
7.3	Awareness	6.2.2	Competence, training, and awareness
7.4	Communication	5.5.3	Internal communications
7.5	Documented information	4.2	Documentation requirements
7.5.1	General	4.2.1	General
		4.2.2	Quality manual
7.5.2	Creating and updating	4.2.3	Control of documents
7.5.3	Control of documented information	4.2.3	Control of documents
		4.2.4	Control of records

**Attachment 1**

ISO9001:2015 Comparison to 9001:2008 – Page 1



8. Operation	7. Product realization
8.1 Operational planning and control	7.1 Planning of product realization
8.2.1 Customer communication	7.2.3 Customer communication
8.2.2 Determination of requirements related to products and services	7.2.1 Determination of requirements related to the product
8.2.3 Review of requirements related to products and services	7.2.2 Review of requirements related to the product
8.3.1 General	
8.3.2 Design and development planning	7.3.1 Design and development planning
8.3.3 Design and development Inputs	7.3.2 Design and development inputs
8.3.4 Design and development controls	7.3.4 Design and development review
	7.3.5 Design and development verification
	7.3.6 Design and development validation
8.3.5 Design and development outputs	7.3.3 Design and development outputs
8.3.6 Design and development changes	7.3.7 Control of design and development changes
8.4 Control of externally provided products and services	7.4 Purchasing
8.4.1 General	7.4.1 Purchasing process
8.4.2 Type and extent of control of external provision	7.4.3 Verification of purchased product
8.4.3 Information for external providers	7.4.2 Purchasing information
8.5 Production and service provision	7.5 Production and service provision
8.5.1 Control of production and service provision	7.5.1 Control of production and service provision
	7.5.2 Validation of processes for production and service provision
8.5.2 Identification and traceability	7.5.3 Identification and traceability
8.5.3 Property belonging to customers or external providers	7.5.4 Customer property
8.5.4 Preservation	7.5.5 Preservation of product
8.5.5 Post-delivery activities	7.5.1 Control of production and service provision
8.5.6 Control of changes	7.2.2 Review of requirements related to the product
8.6 Release of products and services	8.2.4 Monitoring and measurement of product
8.7 Control of nonconforming process outputs, products and services	8.3 Control of nonconforming product
9. Performance evaluation	8. Measurement, analysis, and improvement
9.1.1 General	8.1 General
9.1.2 Customer satisfaction	8.2.1 Customer satisfaction
9.1.3 Analysis and evaluation	8.2.3 Monitoring and measurement of processes
	8.2.4 Monitoring and measurement of product
	8.4 Analysis of data
9.2 Internal audit	8.2.2 Internal audit
9.3 Management review	5.6 Management review
9.3.1 General	5.6.1 General
9.3.1 Performing the review and inputs for the review	5.6.2 Review input
9.3.2 Outputs from the review	5.6.3 Review output
10. Improvement	8.5 Improvement
10.1 General	8.5.1 Continual Improvement
10.2 Nonconformity and corrective action	8.3 Control of nonconforming product
	8.5.2 Corrective action
10.3 Continual improvement	10.3 Continual improvement

### Attachment 1