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ISO 9001:2008
Quality Management System
QMS Manual

QUALITY SYSTEM MANUAL

Approved by/date:	
Spencer Neyland	7 September 2016

QUALITY SYSTEM OPERATIONAL PROCEDURES

QOP-85-02	Customer Complaints	Rev. F
QOP-85-03	Corrective and Preventive Action	Rev. G
1-900-0010	Design Control	Rev.08
1-900-0007	Engineering Changes	Rev.04
1-900-0008	Customer Order	Rev.09
1-901-0005	Supplier Manual	Rev.04
1-901-0010	Engineering Review of Purchasing Dept. Communication With Suppliers	Rev.00
1-911-0036	Control of Property Not Owned By LND, Inc.	Rev.01
1-912-0001	Report of Defects and Noncompliance – 10CFR21	Rev.01
1-913-0005	Customer Returns	Rev.04
1-914-0005	Production Job Folder	Rev.04
1-945-0001	Shipping	Rev.05
1-911-0085	Failure Mode and Effect Analysis	Rev.00
1-904-0007	Creating Production Job Kits	Rev.01
1-911-0039	Internal Audit Checklist	Rev.07

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

Quality System Manual Revisions

REV.	PAGES	CHANGE REQUEST #	DATE	AUTHORIZED BY
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	Update the Index with current QOP revision levels. Add QOP 82-04, Final Inspection to para. 8.2.4.3	ECR 2340	9/8/15	S. Neyland
09	Update the Index with current QOP revision levels.	ECR 2531	9/1/16	S. Neyland

Quality System Manual Availability

Copies of this manual are available online at the LND, Inc. website (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.

1.1 QUALITY POLICY

QUALITY POLICY

"*LND, Inc.* is committed to the continual improvement of the effectiveness of our quality management system and to providing products that satisfy customer and regulatory requirements."

1.2 INTRODUCTION

1.2.1 ***LND, Inc.*** developed and implemented a quality management system to demonstrate its ability to provide products 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.

1.2.2 The quality system complies with the international standard ISO 9001:2008 and government specification MIL-PRF-1N.

1.3 APPLICATION

1.3.1 The quality management system defined in this manual applies to the design, manufacture and distribution of gas-filled nuclear radiation detectors offered by ***LND, Inc***.

1.4 EXCLUSIONS

CLAIMED EXCLUSIONS

No exclusions taken.

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

EU Directive 97/23/EC (PED)

2002/95/EC and 2011/65/EU – Restrictions on Hazardous Substances I & II (RoHS) Directives

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

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

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

2.2 STANDARDS AND GUIDELINES

American National Standard ANSI/ISO/ASQ Q9001-2008, Quality Management system - requirements

American National Standard ANSI/ISO/ ASQ Q9000-2005: 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 10002-2004: Quality Management - Customer Satisfaction – Guidelines for complaint handling in organization

ISO 11118-1999: Gas cylinders – Non-refillable metallic gas cylinders-Specification and test method

3.1 **Audit**: systematic, independent and documented process for obtaining audit 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.

3.3 **Audit evidence**: records, statements of fact or other information, which are relevant to the audit criteria and verifiable (audit evidence may be qualitative or quantitative).

3.4 **Competence**: demonstrated personal attributes and demonstrated ability to apply knowledge and skills.

3.5 **Continual improvement:** Recurring activity to increase the ability to fulfill requirements.

3.6 **Corrective action:** Action to eliminate the cause of a detected nonconformity or other undesirable situation.

3.7 **Customer owned property:** Any type of part, sub-assembly, fixture, accessories, manuals, drawings, computers, software, shipping containers that belong to a customer.

3.8 **Customer satisfaction:** Customer's perception of the degree to which the customer's requirements have been fulfilled.

3.9 **Outsource:** Make an arrangement where an external organization performs part of an organization's function or process.

3.10 **Preventive action:** Action to eliminate the cause of a potential nonconformity or other undesirable potential situation.

3.11 **Product:** The end item of meeting all contract terms and conditions.

3.12 **Quality:** Degree to which a set of inherent characteristics fulfills requirements.

3.13 **Quality assurance:** Part of quality management focused on providing confidence that quality requirements will be fulfilled.

3.14 **Quality control:** Part of quality management focused on fulfilling quality requirements.

3.15 **Quality improvement:** Part of quality management focused on increasing the ability to fulfill quality requirements.

3.16 **Quality management:** Coordinated activities to direct and control an organization with regard to quality.

3.17 **Quality policy:** Overall intentions and direction of an organization related to quality as formally expressed by top management.

4.1 GENERAL REQUIREMENTS

LND, Inc. has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 9001:2008. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

To design and implement the QMS ***LND, Inc.*** has:

- Determined the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram in this section of the Quality Manual
- Determined the sequence and interaction of these processes, and illustrated them on the Process Map Diagram
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective, and documented them in quality plans and work instructions.
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes.
- Established systems to monitor, measure where applicable, and analyze these processes, and
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these process

4.1.1 Outsourced Processes

4.1.1.1 ***LND, Inc.*** has several processes that can be, at times, outsourced to previously approved suppliers. These processes include, but are not limited to, EB welding, materials analysis, nondestructive testing, machining, and plating. The processes that affect product conformity to requirements are controlled by ***LND, Inc***. The nature of the controls depends on the importance of the outsourced process, the risk involved, and the competence of the supplier to meet the process requirements. However, the controls in place shall not inhibit the supplier's from proposing innovations to the outsourced process.

4.1.1.2 Refer to the ***LND, Inc***. Supplier Manual, 1-901-0005 for information pertaining to outsourced processes, supplier responsibilities, evaluation of suppliers and quality program requirements.

4.1.2 Quality system processes

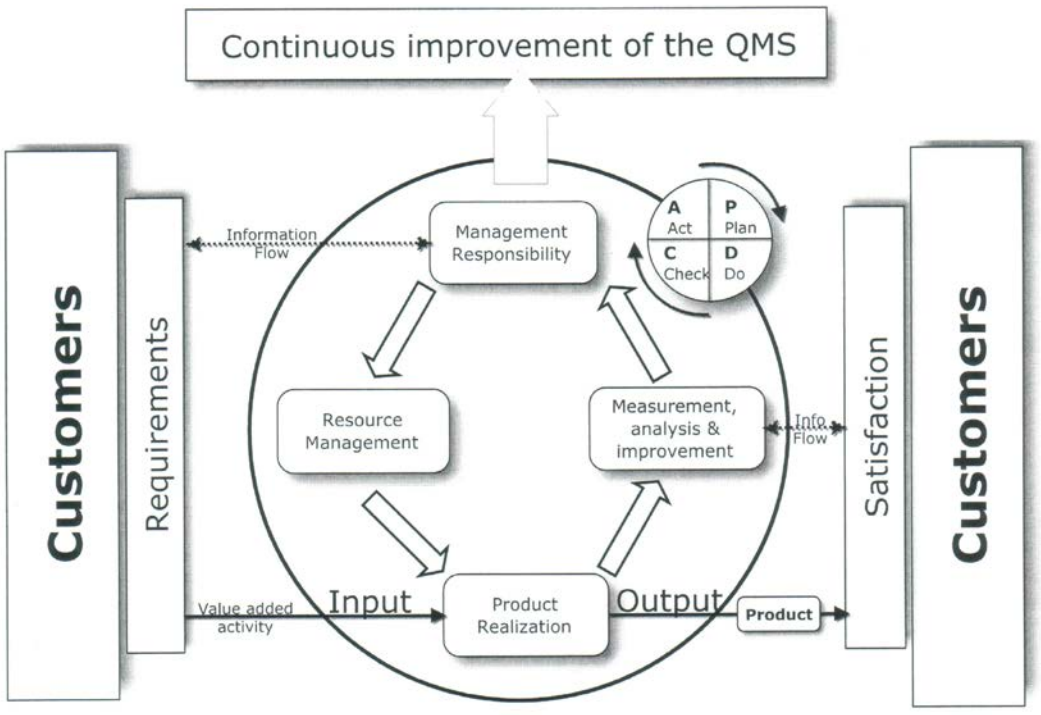
4.1.2.1 The quality management system is designed as a system of interrelated processes. All main activities of the system are defined as Quality System Processes (QSPs) and are grouped into the following four categories (refer to the Process Matrix and Process Map in this section of the Quality Manual):

- 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.

4.1.2.2 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 Processes***.

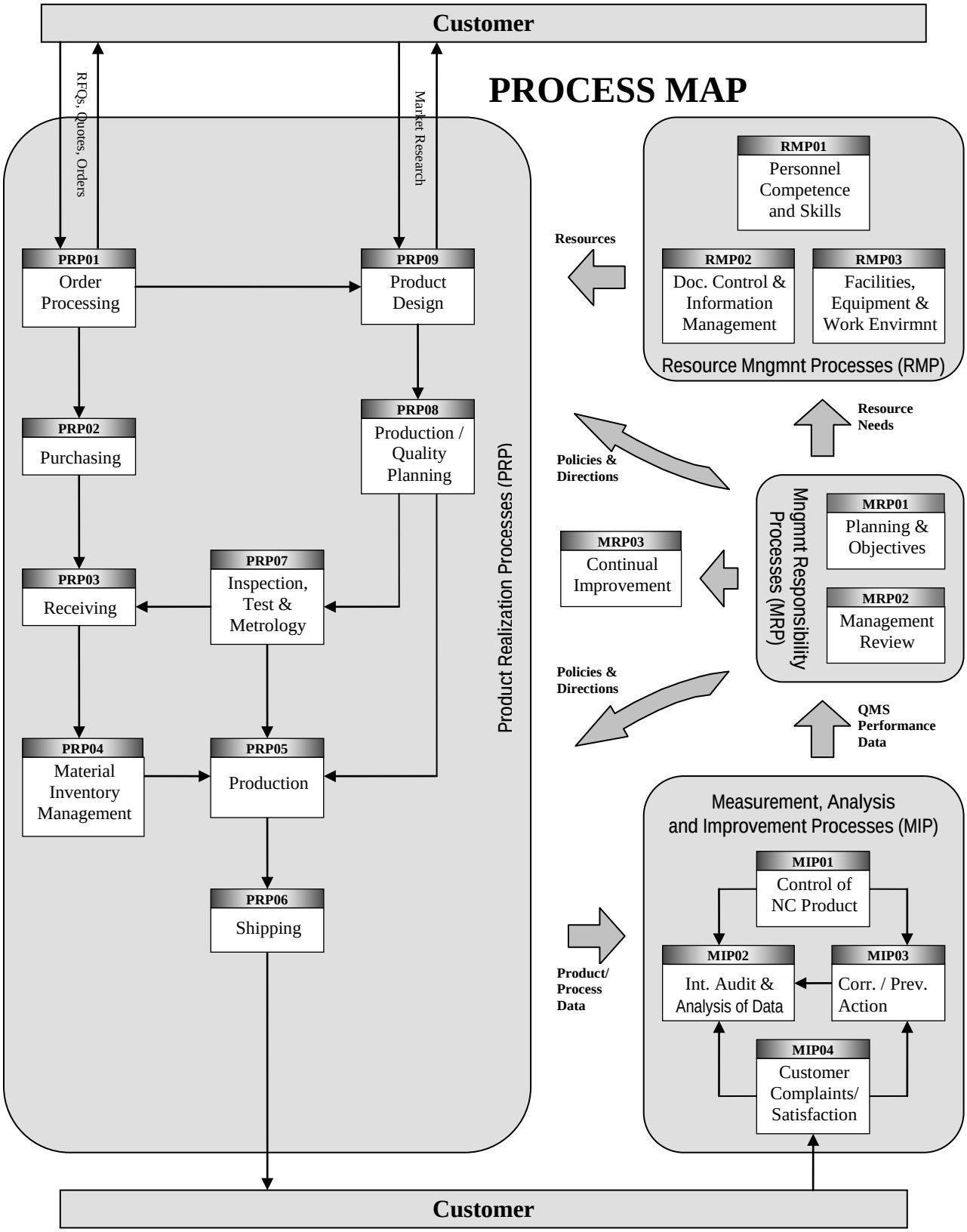
4.1.2.3 Quality system documentation also defines criteria and methods needed to ensure that the operation and control of quality system processes are effective. This includes assignment of responsibilities and allocation of resources for the process, instructions on how to carry out (or operate) the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


Customer
RFQs, Quotes, Orders
Market Research
PRP01
Order Processing
PRP09
Product Design
PRP02
Purchasing
PRP08
Production / Quality Planning
PRP03
Receiving
PRP07
Inspection, Test & Metrology
PRP04
Material Inventory Management
PRP05
Production
PRP06
Shipping
Product Realization Processes (PRP)
Resources
RMP01
Personnel Competence and Skills
RMP02
Doc. Control & Information Management
RMP03
Facilities, Equipment & Work Envirmnt
Resource Mngmnt Processes (RMP)
Resource Needs
Policies & Directions
MRP03
Continual Improvement
MRP01
Planning & Objectives
MRP02
Management Review
Mngmnt Responsibility Processes (MRP)
Policies & Directions
QMS Performance Data
Measurement, Analysis and Improvement Processes (MIP)
MIP01
Control of NC Product
MIP02
Int. Audit & Analysis of Data
MIP03
Corr. / Prev. Action
MIP04
Customer Complaints/ Satisfaction
Product/ Process Data
Customer

PROCESS MAP MATRIX

PRODUCT REALIZATION PROCESSES (PRPs)	
Order Processing	
Purpose	To determine customer requirements, prepare bids and quotations, submit tenders, and take orders from, or enter into contracts with, customers.
Process Owner	Sales
Sub-Processes	• Determining product requirements • Determining customer requirements • Evaluating capability and capacity to meet requirements • Preparing quotations, bids and tenders • Entering orders (or signing contracts) • Receiving, entering and processing change orders • Providing product information
Product Design	
Purpose	To design products meeting the design input requirements.
Process Owner	Engineering
Sub-Processes	• Planning and scheduling design projects • Reviewing and controlling design input • Performing design activities • Conducting design reviews • Establishing design output documents • Verifying and validating product designs • Controlling design changes
Production/Quality Planning	
Purpose	To plan and develop processes needed for manufacturing and verification of product.
Process Owner	Engineering
Sub-Processes	• Determining quality objectives and requirements for products • Developing, validating and documenting production processes (process sheets, equipment setup instructions, tooling specifications, operator instructions, etc.) • Establishing product acceptance criteria and product verification requirements (measuring, inspections, tests, etc)
Purchasing	
Purpose	To select qualified vendors and to purchase from them materials, components, and services necessary for the manufacture and delivery of the product (for full scope of application refer to 1-901-0005, LND Supplier Manual).
Process Owners	Purchasing / Quality
Sub-Processes	• Evaluating and selecting suppliers and subcontractors • Maintaining a list of approved suppliers • Preparing, reviewing and issuing purchasing documents • Communicating with suppliers regarding their quality performance (notifications, requests for corrective actions, etc.)
Receiving	
Purpose	To receive purchased products, visually verify their conformity, and mark/label products with

	their identification and/or acceptance status, as applicable.
Process Owner	Receiving
Sub-Processes	• Receiving purchased products • Visually inspecting incoming products • Applying and/or recording product identification and traceability of incoming products
Material Inventory Management	
Purpose	To receive, store and issue materials, components and parts to be incorporated into finished products.
Process Owner	Stock Room
Sub-Processes	• Operating and maintaining storage areas • Identifying and protecting product in storage • Maintaining special storage conditions/environment • Operating and maintaining the inventory management system
Production	
Purpose	To manufacture products conforming to applicable requirements.
Process Owner	Production
Sub-Processes	• Carrying out manufacturing processes • Monitoring and controlling manufacturing processes • Establishing and maintaining production records • Training process operators and technicians (on-the-job) • Maintaining production equipment and tooling
Delivery	
Purpose	To deliver product to customers and distributors.
Process Owner	Shipping
Sub-Processes	• Processing shipping orders • Packaging and labeling product for shipping • Dispatching or shipping product • Establishing and maintaining shipping and distribution records
Inspection, Test and Metrology	
Purpose	To verify conformity of products, and identification and calibration of monitoring and measuring equipment.
Process Owner	Quality
Sub-Processes	• Monitoring quality performance of suppliers • Verifying purchased product (QC inspection) • Monitoring, measuring, and testing products (in-process and final) • Verifying inspection status identification • Releasing products • Identifying nonconforming products • Selecting, calibrating and controlling the monitoring and measuring equipment
MEASUREMENT AND IMPROVEMENT PROCESSES (MIPs)	
Control of Nonconforming Product	
Purpose	To identify, control and disposition nonconforming products.

Process Owners	Quality / Engineering
Sub-Processes and Procedures	• Identifying, documenting and segregating (where applicable) nonconforming products • Making nonconforming product disposition decisions • Reworking and verifying nonconforming products
Internal Audits and Analysis of Data	
Purpose	To verify conformity of the quality management system, and to evaluate its effectiveness and efficiency.
Process Owner	Quality
Sub-Processes and Procedures	• Conducting internal audits of the quality system • Analyzing and evaluating results of internal, third-party and customer audits • Collecting and analyzing quality performance data
Corrective and Preventive Action	
Purpose	To request, implement and follow up corrective and preventive (C&P) actions.
Process Owner	Quality
Sub-Processes and Procedures	• Evaluating the need for corrective and preventive (C&P) actions • Requesting and implementing C&P actions • Verifying the implementation and effectiveness of C&P actions
Customer Complaints & Satisfaction	
Purpose	To process customer feedback and complaints and to measure customer satisfaction.
Process Owner	Customer Service
Sub-Processes and Procedures	• Receiving and logging customer feedback and complaints • Processing and responding to customer complaints • Gathering of information and data about customer satisfaction • Analyzing, reporting and presenting customer satisfaction information and data (preparing reports, plotting charts, holding meetings, etc)
MANAGEMENT RESPONSIBILITY PROCESSES (MRPs)	
Planning and Objectives	
Purpose	To define the quality policy and quality objectives, to plan the quality management system (QMS), and to implement management commitments.
Process Owner	Management
Sub-Processes and Procedures	• Establishing quality policy • Establishing and monitoring of quality objectives • Planning the quality management system • Defining responsibilities and authorities • Appointing Management Representative
Management Review	
Purpose	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.
Process Owner	Management
Sub-Processes and Procedures	• Presentation, discussion and evaluation of review input information • Determining changes required (if any) for the quality policy, quality objectives and the quality management system

	• Identifying opportunities for improvement and establishing quality objectives
Continual Improvement	
Purpose	To continually improve the quality management system, processes and products.
Process Owner	Management
Sub-Processes and Procedures	• Monitoring performance of the quality management system • Requesting and implementing corrective and preventive actions • Establishing, reviewing and updating the quality policy • Establishing, implementing and monitoring quality objectives • Improving the Quality Management System
RESOURCE MANAGEMENT PROCESSES (RMPs)	
Personnel Competence and Skills	
Purpose	To define competency requirements, provide training, and ensure awareness about quality-related issues.
Process Owner	Operations / Quality
Sub-Processes and Procedures	• Determining competency requirements for jobs/positions affecting product quality • Providing training and/or taking other actions to satisfy competency requirements • Evaluating the effectiveness of training • Providing awareness programs to ensure employee motivation, empowerment, and knowledge of quality-related issues
Document Control and Information Management	
Purpose	To control documents related to products, manufacturing processes and the quality system; and to control quality records.
Process Owner	Tech Comm
Sub-Processes and Procedures	• Establishing documents needed by the organization • Reviewing and approving documents • Controlling document revisions and distribution (availability) • Managing retention, storage, and disposition of records
Facilities, Equipment and Work Environment	
Purpose	To ensure appropriate and adequate facilities, production equipment and supporting services.
Process Owner	Operations
Sub-Processes and Procedures	• Plant, facility and equipment planning • Maintaining plant, facilities and manufacturing process equipment

4.2 DOCUMENTATION REQUIRED

4.2.1 General

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

- A documented Quality Policy and quality objectives;
- Quality Manual;
- Quality system operational procedures and records;
- Quality system forms;
- Work instructions;

- Product labeling and packaging specifications;
- Manufacturing specifications;
- Quality assurance/control procedures, records 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.***

4.2.2 Quality Manual

This Quality Manual has been prepared to describe ***LND, Inc.'s*** QMS. The scope and permissible exclusions (if any) of the QMS are described in Section 01 of this manual. Each section of the manual references documented QMS procedures relating to the requirement outlined in that section. The Process Flow Diagram at the end of Section 04 provides a description of the interaction between the processes of the QMS system.

4.2.3 Control of documents

4.2.3.1 ***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***.

4.2.3.2 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.

4.2.4 Control of records

4.2.4.1 Records are 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 Records*** defines specifically what records are maintained in each category and designates their storage locations, retention periods and disposal. It also defines the process for ensuring that records are

legible, readily identified, are stored in appropriate locations and conditions, are adequately protected, and are easily retrievable.

5.1 MANAGEMENT COMMITMENT

5.1.1 Top management has been actively involved in implementing the quality management system (QMS). Top management has provided the vision and strategic direction for growth of the QMS, and established quality objectives and the quality policy.

To continue to provide leadership and show commitment to the improvement of the QMS, top management shall do the following;

- Communicate the importance of meeting customer, statutory and regulatory requirements,
- Ensuring that quality objectives are established,
- Establish a quality policy,
- Conduct annual management reviews, and
- Ensure the availability of resources.

5.2 CUSTOMER FOCUS

5.2.1 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.

5.2.2 Top management ensures that customer requirements 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 7.2.1 Determination of Requirements Related to the Product*** and ***QM Section 7.2.2 Review of Requirements Related to the Product***, and in associated operational procedures.

5.2.3 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 8.2.4 Monitoring and Measurement of Product***, and in associated operational procedures.

5.2.4 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 8.2.1 Customer Satisfaction***, and in the associated operational procedure.

5.3 QUALITY POLICY

5.3.1 Quality policy is documented in this manual in ***QM Section 01, Para. 1.1 Quality Policy***.

5.3.2 Quality policy is established by top management. In formulating the quality policy, top management ensures that the policy is appropriate to the purpose of the company, and includes a commitment to comply with the requirements and continually improve the effectiveness of the quality management system.

5.3.3 Quality policy provides a framework for establishing specific quality objectives, and provides direction for the continual improvement effort. The use of the quality policy in setting quality objectives is addressed in this manual in ***QM Section 05, Para. 5.4.1 Quality Objectives***.

5.3.4 Quality policy is posted throughout the company, and its role is explained and discussed at the general orientation training provided to all new employees. 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.

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

5.4 PLANNING

5.4.1 Quality objectives

5.4.1.1 Top management ensures that quality objectives are established throughout the organization to implement the quality policy, to meet requirements for products and processes, and to improve the quality system and quality performance.

5.4.1.2 Quality objectives are measurable, and reviewed against performance goals at each management review meeting.

5.4.2 Quality management system planning

5.4.2.1 Top management shall ensure that quality management system processes are planned and implemented to meet the company's quality objectives and the requirements of ***QM Section 04, Para. 4.1 General Requirements*** and the integrity of the quality management system are maintained when changes to the QMS are planned and implemented.

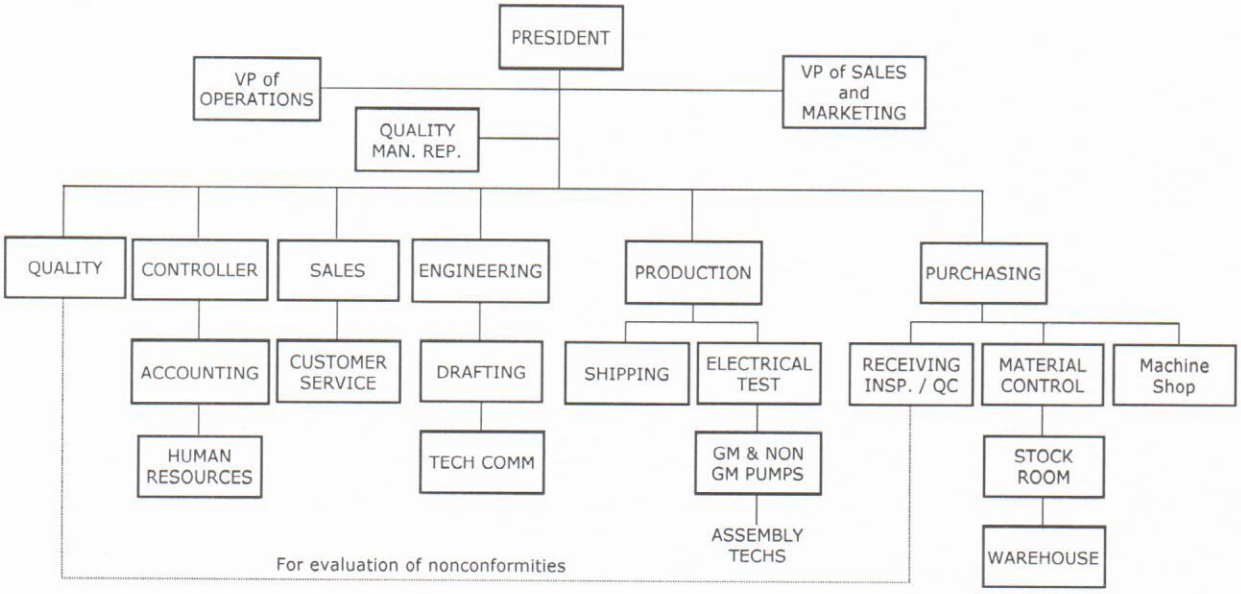
5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

5.5.1.1 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 05, Para. 5.5.1***.

5.5.1.2 Top management shall ensure that authorities and responsibilities for specific processes of the quality management system are defined and communicated:

- Throughout this quality manual and in every operational procedure where the specific quality system process or activity is documented;
- In Quality System Process Matrix sheets in ***QM Section 04, Para. 4.1.1*** (as Process Owners); and
- In job descriptions.



LND, INC. ORGANIZATIONAL CHART

5.5.2 Management Representative

5.5.2.1 Top management has appointed the Vice President of Operations as the Management Representative for the quality management system. Management Representative has the authority and responsibility to:

- Ensure that processes needed for the quality management system are established, implemented and maintained;
- Promote awareness of customer requirements throughout the organization;
- Report to the top management on the performance of the quality management system and any need for improvement, and
- Coordinate communication with external parties on matters relating to the quality management system and ISO 9001 registration.

5.5.3 Internal communication

5.5.3.1 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, management reviews, circulation of minutes of management review meetings, internal audit closing meetings, and other routine business communication.

5.6 Management review

5.6.1 General

5.6.1.1 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). Records are maintained for each management review meeting. Refer to Operational Procedure ***QOP-56-01, Management Review***.

5.6.2 Review input

5.6.2.1 Input into the management reviews consists of information and data related to quality performance of the organization. At a minimum, this includes:

- Follow-up actions from earlier management reviews,
- Process performance and product conformity data,
- Status of preventive and corrective actions,
- Customer feedback and complaints,
- Results of audits,
- Status of quality objectives,
- Changes that could affect the quality management system, and
- Recommendations for improvement.

5.6.3 Review output

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

- Improvement of the effectiveness of the QMS and its processes
- Improvement of product related to customer requirements, and
- Resource needs.

5.6.3.2 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.

6.1 PROVISION OF RESOURCES

6.1.1 ***LND, Inc.*** has implemented a Quality Management System that complies with the ISO 9001:2008 standard and enhances customer satisfaction by meeting customer requirements. This implementation was achieved with top management commitment and with sufficient resources for the implementation to effectively maintain and continually improve the system. Management determines and provides necessary resources.

6.2 HUMAN RESOURCES

6.2.1 General

6.2.1.1 Personnel performing work affecting conformity to product requirements are competent. Competency is determined on the basis of appropriate education, training, skills and experience. Conformity to product requirements may be affected by personnel who are directly or indirectly responsible for tasks within the quality management system.

6.2.1.2 Operations is responsible for training and awareness programs for company-wide participation, such as: general orientation, rules and regulations, quality system, safety, and other company-wide systems and issues.

6.2.1.3 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.

6.2.2 Competence, awareness and training

6.2.2.1 The objective of the company's training program is to ensure that employees possess the required knowledge and skills for performing their jobs; and that they are familiar with relevant requirements of the quality system pertaining to their job functions.

6.2.2.2 Awareness programs focus on understanding the importance of customer requirements, and the relevance of individual contributions towards meeting these requirements and achieving the quality policy and objectives.

6.2.2.3 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 records.

6.3 INFRASTRUCTURE

6.3.1 Buildings, workspace and associated utilities

6.3.1.1 Infrastructure and facilities, such as buildings, workspaces and associated utilities, etc., are appropriate and are properly maintained to achieve conformity to product requirements.

6.3.1.2 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.

6.3.1.3 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. Extensive repairs of buildings and other such facilities are contracted as needed. Purchasing is responsible for coordinating and managing maintenance contracts.

6.3.2 Process equipment

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

6.3.3 Supporting services

6.3.3.1 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 Supplier Evaluation and Monitoring***, and ***1-901-0005, LND Supplier Manual.***
- 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 Supplier Evaluation and Monitoring***, and ***1-901-0005, LND Supplier Manual***. Normal day-to-day operations of the IT systems are controlled and maintained by the President (AS400), Testing (PICS System) and Draftsman (Design/Drafting).

6.3.4 Equipment Maintenance

6.3.4.1 Key process equipment, machines, hardware, and software are regularly maintained in accordance with maintenance plans specified by equipment manufacturers or department managers responsible for the equipment. Requirements for the maintenance of production equipment are specified in Operational Procedure ***QOP-63-01 Equipment Maintenance***.

6.4 WORK ENVIRONMENT

6.4.1 Human factors

6.4.1.1 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. (Refer to Operational Procedure ***QOP-62-01 Competence, Awareness and Training***.)

6.4.2 Physical factors

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

6.4.3 Health and safety

6.4.3.1 Health and safety management system is independent from the quality management system. It is administrated by Operations and is documented in the Health and Safety (H&S) manual.

7.1 PLANNING OF PRODUCT REALIZATION

7.1.1 Production and quality planning

7.1.1.1 Quality planning is required before new products or processes are implemented. The planning includes the determination of:

- Requirements and quality objectives for products 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 product acceptance; and
- Records needed to provide evidence that the realization process and resulting product and processes meet requirements.

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

7.2 CUSTOMER-RELATED PROCESSES

7.2.1 Determination of requirements related to the product

7.2.1.1 ***LND, Inc.*** determines customer requirements before acceptance of an order. Customer requirements include:

- Requirements specified by the customer, including delivery and post-delivery (e.g. actions under warranty, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal) activities;
- Requirements not stated by the customer, but necessary for specified use or intended use, where known;
- Statutory and regulatory requirements applicable to the product, and
- Any additional requirements considered necessary by the company.

7.2.2 Review of requirements related to the product

7.2.2.1 Prior to the commitment to supply a product to the customer, orders are reviewed to ensure that:

- Product requirements are defined;
- Any ambiguities and conflicts in contract or order requirements are resolved; and
- The company is able to meet customer requirements.

7.2.2.2 Records of the results of the review and any associated actions are maintained. Refer

to ***QM Section 4.2.4, Control of Records***.

7.2.2.3 When the customer provides no documented statement of requirements (as with verbal orders), the customer requirements are confirmed before acceptance.

7.2.2.4 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.

7.2.2.5 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.

7.2.3 Customer communication

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

- Product information,
- Enquiries, contracts and order handling, including amendments, and
- Customer feedback, including customer complaints.

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

7.2.3.3 Arrangements for communicating with customers regarding customer feedback and complaints are defined in Operational Procedures ***QOP-82-01 Customer Satisfaction*** and ***QOP-85-02 Customer Complaints***.

7.3 DESIGN AND DEVELOPMENT

7.3.1 Design and development planning

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

7.3.1.2 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.

7.3.2 Design and development inputs

7.3.2.1 Design input requirements are developed by Engineering from product concepts, such as product 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,
- Applicable statutory and regulatory requirements,

- Information derived from previous similar designs (when applicable), and
- Other requirements essential for design and development.

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

7.3.2.3 Records are maintained in accordance with ***QM Section 4.2.4, Control of Records*.**

7.3.3 Design and development outputs

7.3.3.1 Design and development outputs are documented, checked and verified against design and development inputs, and approved before they are released for production. Design and development outputs;

- Meet the design and development input requirements,
- Provide appropriate information for purchasing and production,
- Contain or reference product acceptance criteria, and
- Specify the characteristics of the product that are essential for safe and proper use.

7.3.4 Design and development reviews

7.3.4.1 Design reviews are carried out at appropriate stages in accordance with the design project plan. The purpose of the design reviews is to evaluate the ability of the design to meet design input requirements, and to identify any problems and propose necessary actions.

7.3.4.2 Participants in design reviews include representatives of functions concerned with the design stage being reviewed, as well as other specialist personnel.

7.3.4.3 Records of the results of the review and any necessary actions are maintained in accordance with ***QM Section 4.2.4, Control of Records***.

7.3.5 Design and development verification

7.3.5.1 Product designs are verified in accordance with planned arrangements (design and development project plan). The purpose is to ensure that the design and development outputs have met the design and development input requirements.

7.3.5.2 Records of the results of product design verification, and any necessary actions, are maintained in accordance with ***QM Section 4.2.4, Control of Records***.

7.3.6 Design and development validation

7.3.6.1 Product designs and development are validated in accordance with planned arrangements (design and development project plan) and that the resulting product is capable of meeting the requirements for specified application or intended use, where known.

7.3.6.2 Validation is completed prior to the delivery or implementation of the product, when practical.

7.3.6.3 Records of the results of product design validation, and any necessary actions, are maintained in accordance with ***QM Section 4.2.4, Control of Records***.

7.3.7 Control of design and development changes

7.3.7.1 Design and development changes are initiated, processed and controlled using the Engineering Change Request (ECR) system defined in Operational Procedure ***1-900-0007, Engineering Changes***. Design changes are reviewed, verified and validated as appropriate, and approved before implementation.

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

7.3.7.3 Records of the results of review of changes, and any necessary actions, are maintained in accordance with ***QM Section 4.2.4, Control of Records***.

7.4 PURCHASING

7.4.1 Purchasing process

7.4.1.1 A documented procedure, ***Verification of Purchased Product QOP-74-03***, is followed to ensure that purchased product conforms to the specified purchase requirements.

7.4.1.2 ***LND, Inc***. has developed a ***Supplier Manual (1-901-0005)*** that outlines the extent of control and responsibilities required by the suppliers. Suppliers are evaluated and selected based on their ability to supply product in accordance with the requirements outlined in the Supplier Manual. Criteria for selection, evaluation and re-evaluation are documented in the Operational Procedure ***QOP-74-01, Supplier Evaluation and Monitoring***.

7.4.1.2 Records of the evaluation and any necessary actions are maintained as quality records.

7.4.2 Purchasing information

7.4.2.1 Purchasing documents clearly and completely describe the ordered products, including;

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

7.4.2.2 Purchasing documents are reviewed for adequacy of requirements and approved prior to orders being placed with suppliers.

7.4.3 Verification of purchased product

7.4.3.1 Purchased products 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 Product*** defines the processes for verifying, identifying and releasing purchased products.

7.4.3.2 If verification of purchased product is ever performed at the supplier's facility, purchasing documents specify the intended verification arrangements and method of product release.

7.5 PRODUCTION PROVISION

7.5.1 Control of production

Product manufacturing is carried out under controlled conditions. The controlled conditions include the control of, as applicable:

- The availability of information that describes the characteristics of the product,
- The availability of work instructions (PICS system procedures),
- The use of suitable equipment,
- The availability and use of monitoring and measuring equipment,
- The implementation of monitoring and measurement, and
- The implementation of release, delivery and post-delivery activities.

7.5.2 Validation of processes for production provision

7.5.2.1 ***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 records, and
- Revalidation.

7.5.3 Identification and traceability

7.5.3.1 **Identification:** Materials, components and 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 are explained in Operational Procedure ***QOP-74-03 Verification of Purchased Product***.

7.5.3.2 **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, or batches, with unique control numbers. Activities related to maintaining and recording traceability are addressed in

Operational Procedures ***QOP-74-03 Verification of Purchase Product***.

7.5.3.3 **Product status:** Throughout product realization, and when in storage, products 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 Product***.

7.5.4 Customer property

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

7.5.5 Preservation of product

7.5.5.1 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. Operational Procedure ***QOP-75-05 Storage, Handling and Preservation*** define how these policies are implemented.

7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT

7.6.1 ***LND, Inc***. has determined the monitoring and measurements to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The procedure, ***QOP-76-01 Measuring and Monitoring Equipment***, 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 measurement requirements.

7.6.1.1 When necessary to ensure valid results, measuring equipment is;

- Calibrated or verified at specific intervals, or prior to use, against measurement standards traceable to international or national measurement standards,
- Adjusted or re-adjusted as necessary,
- Identified to enable the calibration status to be determined,
- Safeguarded from adjustments that would invalidate the measurement results, and
- Protected from damage and deterioration during handling, maintenance and storage.

7.6.1.2 Quality Assurance assesses and records 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 product affected. Records of the results

of calibration and verification are maintained.

7.6.1.3 When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary. Confirmation of software includes verification and configuration to maintain its suitability for use.

8.1 GENERAL

8.1.1 ***LND, Inc***. plans and implements the monitoring, measurement, analysis and improvement processes needed;

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

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

8.2 MONITORING AND MEASUREMENT

8.2.1 Customer satisfaction

8.2.1.1 As one of the measurements of the performance of the quality management system, ***LND Inc***. monitors information relating to customer perception as to whether the company has met customer requirements.

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

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

8.2.2 Internal audit

8.2.2.1 Quality is responsible for coordinating the internal audits of the quality management system at planned intervals to determine whether the quality system:

- Conforms to planned arrangements (refer to ***QM Section 7.1, Planning of Product Realization***), to the quality management system requirements as defined in this quality manual and operational procedures, and to the requirements of the ISO 9001 standard,
- Is effectively implemented and maintained.

8.2.2.2 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.

8.2.2.3 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.

8.2.2.4 Records of the audit and its results shall be maintained in accordance with ***QM Section 4.2.4, Control of Records.***

8.2.2.5 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.

8.2.3 Monitoring and measurement of processes

8.2.3.1 ***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 product requirements and on the effectiveness of the quality management system.

8.2.3.2 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 and Preventive Action***.

8.2.4 Monitoring and measurement of product

8.2.4.1 ***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 Production Process flowchart, Section 4.1.1.3 of this manual.

8.2.4.2 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 Records.***

8.2.4.3 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***.

8.3 CONTROL OF NONCONFORMING PRODUCT

8.3.1 Identification and documentation

8.3.1.1 ***LND, Inc***. ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in Operational Procedure ***QOP-83-01 Control of Nonconforming Product***.

8.3.1.2 ***LND, Inc***. deals with nonconforming product 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 product is detected after delivery or use has started.

8.3.1.3 Records 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 Records.***

8.3.1.4 When nonconforming product is corrected it is subject to re-verification to demonstrate conformity to the planned requirements.

8.4 ANALYSIS OF DATA

8.4.1 General

8.4.1.1 Data and information recorded in quality records are compiled and analyzed periodically to determine trends in the performance and effectiveness of the quality management system and to identify opportunities for improvement.

8.4.1.2 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.

8.4.1.3 The analysis of data provides information relating to;

- Customer satisfaction,
- Conformance to product requirements,
- Characteristics and trends of processes and products including opportunities for preventive action, and
- Suppliers.

8.5 IMPROVEMENT

8.5.1 Continual improvement

8.5.1.1 ***LND, Inc.*** continually 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 and preventive actions and management review.

8.5.2 Corrective and preventive action

8.5.2.1 Corrective actions are taken to eliminate causes of nonconformities in order to prevent their recurrence.

8.5.2.2 Preventive actions are implemented to eliminate causes of potential nonconformities in order to prevent their occurrence.

8.5.2.3 The process for taking corrective and preventive actions includes requirements for:

- Reviewing nonconformities and determining potential nonconformities,
- Determining causes for nonconformities and potential nonconformities,
- Evaluating the need for action to ensure that nonconformities do not recur and that potential nonconformities are prevented,
- Determining and implementing actions needed, including, if appropriate, updating documentation,
- Recording the results of any investigations and of actions taken, and
- Reviewing the corrective or preventive action taken and its effectiveness.

8.5.2.4 This process is defined in Operational Procedure ***QOP-85-03 Corrective and Preventive Action***.

ISO 9001:2008	Clause	Criterion	10CFR50 Appendix B
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Determination of requirements related to the product	7.2.1	7	Control of purchased material, equip. & svcs.

Approved by/date:	
Spencer Neyland	6 January 2010

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