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ISO 9001:2015
Quality Management System
Manual

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

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
10	Removed QOP/WI listing from index. Deleted old call-out for PED directive. Revised Terms and Definitions.	ECR 2695	12/14/17	S. Neyland
11	Update manual to the ISO9001:2015 standard.	ECR 2757	1/30/18	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 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, BF3 and 3He 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.

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

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

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

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.

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.

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 and Preventive 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.

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-PRF-1.

4.3.2 The ***LND, Inc.*** Quality System Manual is a top-level or Level 1 document, along with 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):

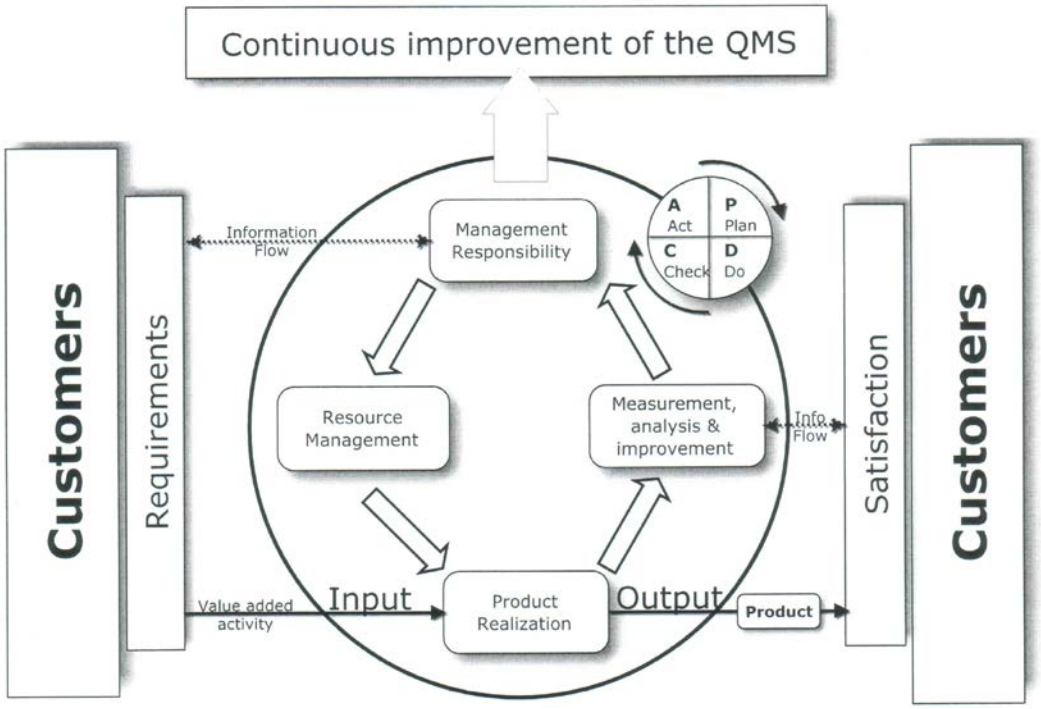
- Product Realization Processes (PRP),
- Measurement, Analysis and Improvement Processes (MIP),
- Management Responsibility Processes (MRP), and
- Resource Management Processes (RMP)

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 Processes***.

Quality system documentation also defines criteria and methods needed to

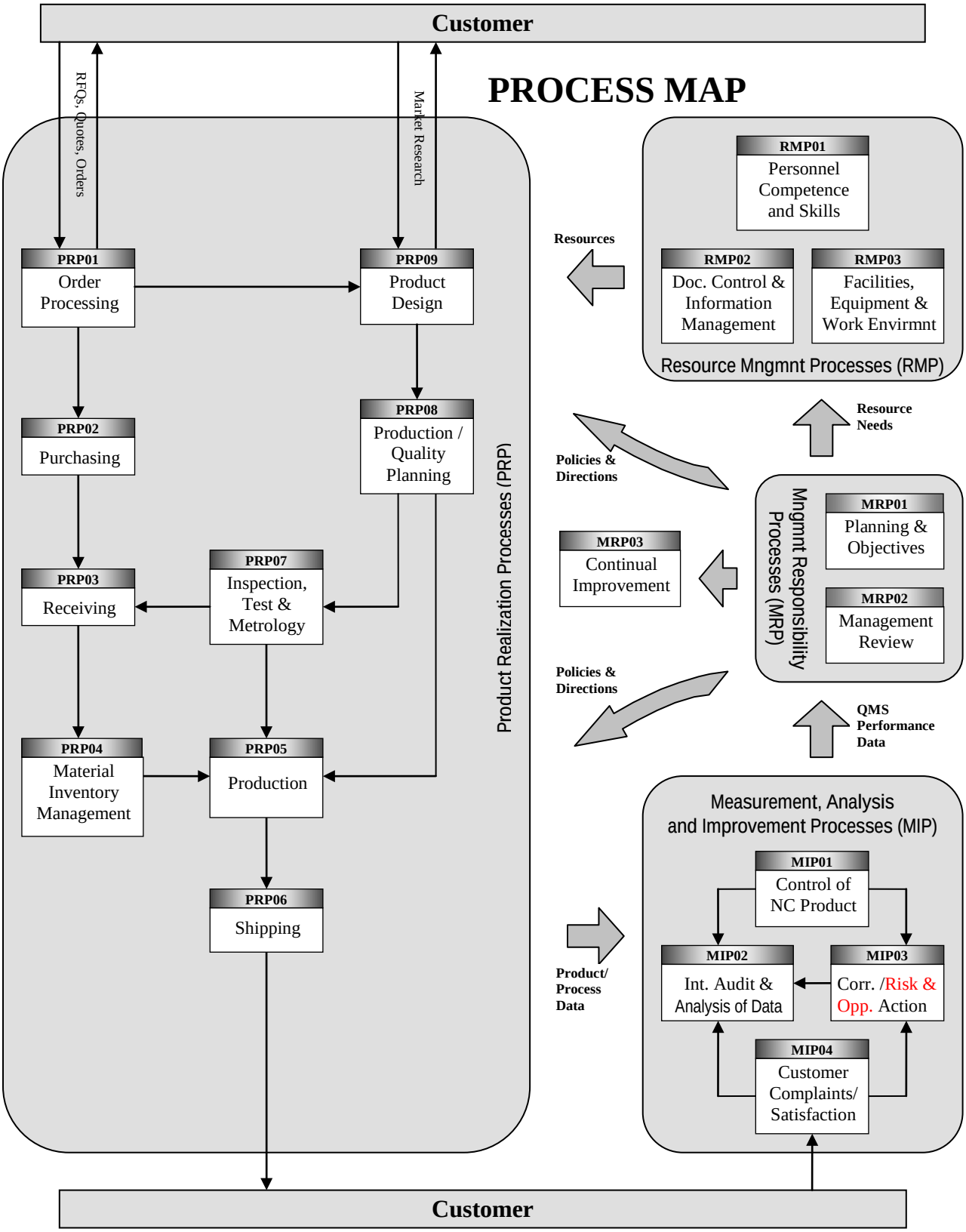
ensure that the operation and control of quality system processes are effective. This includes assignment of responsibilities and allocation of resources for the process, instructions on how to carry out (or operate) the process, and definition of methods for monitoring and/or measuring the effectiveness 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. /Risk & Opp. 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 products and services 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 products and services information
Product Design	
Purpose	To design products and services 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 documented information • Verifying and validating products and services designs • Controlling design changes
Production/Quality Planning	
Purpose	To plan and develop processes needed for manufacturing and verification of products and services.
Process Owner	Engineering
Sub-Processes	• Determining quality objectives and requirements for products and services • Developing, validating and documenting production processes (process sheets, equipment setup instructions, tooling specifications, operator instructions, etc.) • Establishing products and services acceptance criteria and products and services verification requirements (measuring, inspections, tests, etc)
Purchasing	
Purpose	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).
Process Owners	Purchasing / Quality
Sub-Processes	• Evaluating and selecting external providers and subcontractors • Maintaining a list of approved external providers • Preparing, reviewing and issuing purchasing documented information • Communicating with external providers regarding their quality performance (notifications, requests for corrective actions, etc.)
Receiving	

Purpose	To receive purchased products and services, 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 and services.
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 and services conforming to applicable requirements.
Process Owner	Production
Sub-Processes	• Carrying out manufacturing processes • Monitoring and controlling manufacturing processes • Establishing and maintaining production documented information • 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 products and services • Establishing and maintaining shipping and distribution documented information
Inspection, Test and Metrology	
Purpose	To verify conformity of products and services, and identification and calibration of monitoring and measuring equipment.
Process Owner	Quality
Sub-Processes	• Monitoring quality performance of external providers • Verifying purchased product (QC inspection) • Monitoring, measuring, and testing products (in-process and final) • Verifying inspection status identification • Releasing products and services • Identifying nonconforming products and services • Selecting, calibrating and controlling the monitoring and measuring equipment
MEASUREMENT AND IMPROVEMENT PROCESSES (MIPs)	
Control of Nonconforming Products and Services	
Purpose	To identify, control and disposition nonconforming products and services.

Process Owners	Quality / Engineering
Sub-Processes and Procedures	• Identifying, documenting and segregating (where applicable) nonconforming products and services • Making nonconforming products and services disposition decisions • Reworking and verifying nonconforming products and services
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, Risk and Opportunity Actions	
Purpose	To request, implement and follow up corrective, risk and opportunity actions.
Process Owner	Quality
Sub-Processes and Procedures	• Evaluating the need for corrective, risk and opportunity actions • Requesting and implementing corrective, risk and opportunity actions • Verifying the implementation and effectiveness of corrective, risk and opportunity 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 and services.
Process Owner	Management
Sub-Processes and Procedures	• Monitoring performance of the quality management system • Requesting and implementing corrective, risks and opportunities • 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 products and services 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 documented information related to products and services, manufacturing processes and the quality system; and to control quality documented information.
Process Owner	Tech Comm
Sub-Processes and Procedures	• Establishing documented information needed by the organization • Reviewing and approving documented information • Controlling document revisions and distribution (availability) • Managing retention, storage, and disposition of documented information
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

5.1 Leadership and Commitment

5.1.1 General – ***LND, Inc.*** top management defines, develops and implements the quality management system per Operational Procedure ***QOP 56-01, Management Review Report***.

Top management demonstrates leadership and ensures that employees at all levels of the organization understand the goals and objectives of the ***LND, Inc.*** quality management system.

LND, Inc. conducts annual Management Review Meetings and discusses the importance of meeting the following:

- Customer requirements,
- Statutory, legal and regulatory requirements,
- Quality objectives,
- Quality policy,
- Continuous improvement goals,
- Availability of resources,
- Risk analysis,
- Interested parties.

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 Requirements Related to the Products and Services*** and ***QM Section 8.2.2 Review of Requirements Related to the Products and Services***, and in associated operational procedures.

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 9.2.4 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 of the company, and includes a commitment to comply with the requirements and continually improve the effectiveness of the quality management system.

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 6, Para. 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.

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

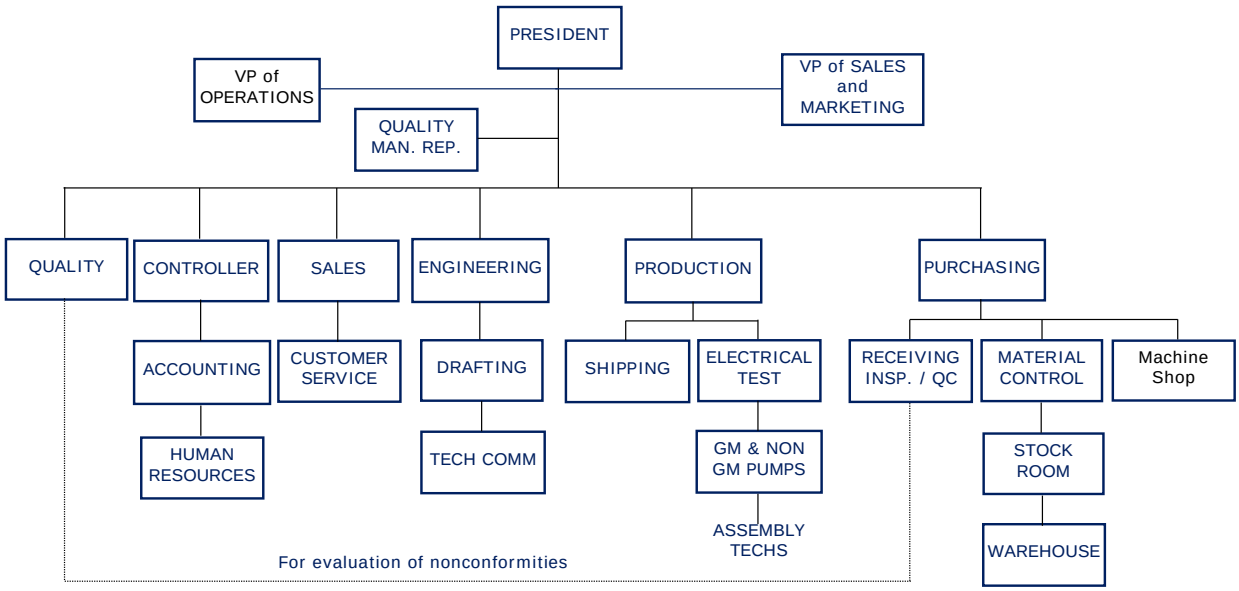
5.3 Organizational roles, responsibilities and authorities

LND, Inc. defines the responsibilities and authorities of stall 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 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 4, Para. 4.4*** (as Process Owners); and
- In job descriptions.



LND, INC. ORGANIZATIONAL CHART

5.3.1 Management Representative

Top management has appointed the Vice President of Operations as the Management Representative for the quality management system. The Management Representative has sufficient independence and authority to ensure nuclear safety related activities are performed to requirements and Quality System requirements are maintained. Management Representative is authorized and responsible for:

- Ensuring that processes needed for the quality management system are implemented, maintained and continually improved;
- Promoting awareness of customer requirements throughout the organization;
- Report to the top management on the performance of the quality system, including needs for improvement, and
- Coordinating communication with external parties on matters relating to the quality system and ISO 9001 registration.

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 LND procedure ***1-911-0095, Risk Analysis***.

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, Inc.*** manufactures its products according to customer specifications, documented engineering drawings, pump and fill schedules, assembly procedures, inspection and test procedures, and technical specifications Documentation is recorded and retained as per Operational Procedures ***QOP 42-01, Control of Documents***, and ***QOP 42-02, Control of Records***.

6.1.3 Preventive Action – ***LND, Inc.*** preventive action process is identified in LND Operational Procedure ***QOP 85-03, Corrective and Preventive Action,*** which includes the following:

- Use of appropriate sources of information to detect, analyze, and eliminate potential causes of nonconformities.
- Determining the steps needed to deal with any problems requiring preventive action.
- Initiating preventive action and applying controls to ensure that it is effective.
- Ensuring that relevant information on actions taken, including changes to procedures, is submitted for management review.

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 Product)***.

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, Para. 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.

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.

7.1.3 Infrastructure – *LND, Inc.* provides and maintains buildings, workspace, equipment, and support services needed to achieve conformity to product 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.***

- 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 IT systems are controlled and maintained by the President (AS400), Testing (PICS System) and Draftsman (Design/Drafting).

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 Health and Safety (H&S) manual.

7.1.5 Monitoring and measuring resources

7.1.5.1 General - ***LND, Inc***. has determined the monitoring and measurements to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of products and services 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.

7.1.5.2 Measurement Traceability – Following elements comprise the LND calibration system:

- Inspection and test equipment is selected and used based on desired attribute to be evaluated and the degree of accuracy required.
- Calibration is performed on applicable equipment at scheduled intervals based on the complexity, frequency of use, and calibration performance.

- The calibration system utilizes documented procedures that are established and maintained that define calibration criteria, procedures, equipment, and out-of-calibration action (impact on product produced).
- Calibrated equipment is positively identified by a system that permits for indication when previously calibrated and next due date.
- Calibration records are maintained for all inspection, measuring and test equipment.
- Equipment is used and stored in locations adequate to ensure accuracy and fitness for use.
- Measurement standards are controlled to assure against misuse/abuse.
- Calibrations are performed with use of standards that are traceable to units of measure through NIST.

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. 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.

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 Records***.

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 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, 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.

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.

7.5.2.2 Control of Quality Records

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.

7.5.3 Control of documented information – Covered in section 7.5.2.

8.1 Operational planning and control

8.1.1 Quality 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; and
- Documented information needed to provide evidence that the realization process and resulting products and services, and processes meet requirements.

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

8.2 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:

- Products and services information,
- Enquiries, contracts and order handling, including amendments, and
- Customer views and perception, including customer complaints.

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 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 4.2.4, 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***.

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 4.2.4, 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 and records of such reviews are maintained.

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.

8.3.5 Design and development outputs

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,
- Contain or reference product acceptance criteria,
- Specify the characteristics of the product that are essential for safe and proper use, and
- Review of design output documents before release.

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 approved before 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 4.2.4, 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 Product*** is followed to ensure that purchased products and services conform to the specified purchase requirements.

8.4.2 Type and extent of control

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. External providers are evaluated and selected based on their ability to supply products and services 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, External Provider Evaluation and Monitoring***.

8.4.2.3 Documented information of the evaluation and any necessary actions are maintained as quality records.

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

8.4.2.5 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 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.

8.4.3.3 If verification of purchased product is ever performed at the external provider's facility, 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 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 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***.

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 Product***.

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 Product***.

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.

8.5.4 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. 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.

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 Production Process flowchart, 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 Records~~.~~***

~~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 process 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.

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, Risk and Opportunity 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.

8.7.4 When nonconforming products and services are corrected it is subject to re-verification to demonstrate conformity to the planned requirements.

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.

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 system:

- Conforms to planned arrangements (refer to ***QM Section 7.1, Planning of Products and Services 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.

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 4.2.4, 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 and data related to quality performance of the organization. At a minimum, this includes:

- Process performance and products and services conformity data,
- 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 open items from previous MRM meetings,
- Opportunities for improvement,
- CAPA status report,
- Changes in external and internal issues,
- Adequacy of resources,

- New issues,
- Performance of external providers (annual report),
- Calibration performance (annual report),
- 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.

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, 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.

- 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 and Preventive 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. See Sections 6.1 and 10.1.

10.3.1 Should a recall of LND products be necessary, LND procedure ***1-900-0023, Product Recall*** is followed.

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 4.1	General General requirements
4.2	Understanding the needs and expectations of interested parties	1.1 7.2.1	General Determination of requirements related to the product
4.3	Determining the scope of the quality management system	1.2 4.2.2	Application Quality manual
4.4	Quality management system and its processes	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 5.5.2	Responsibility and authority Management representative
6.	Planning for the quality management system		
6.1	Actions to address risks and opportunities	5.4.2 8.5.3	Quality management system planning 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 4.2.2	General Quality manual
7.5.2	Creating and updating	4.2.3	Control of documents
7.5.3	Control of documented Information	4.2.3 4.2.4	Control of documents Control of records

Attachment 1

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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 7.3.5 7.3.6	Design and development review Design and development verification 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 7.5.2	Control of production and service provision 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 8.2.4 8.4	Monitoring and measurement of processes Monitoring and measurement of product 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 8.5.2	Control of nonconforming product Corrective action
10.3	Continual improvement	10.3	Continual improvement

Attachment 1

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