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of Transportation  
**Federal Aviation  
Administration**

**Transport Airplane Directorate  
Aircraft Certification Service**  
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Inspection District Office  
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Lakewood, CA 90712-4137

April 27, 2016

Leach International  
Attn: Jack Brooks  
6900 Orangethorpe Ave.  
Buena Park, CA 90622

### **Notification of Quality System Change Status**

Dear Mr. Brooks:

We have completed our review and evaluation of your Quality Control System changes documented in your Quality Assurance Manual. Your submitted data meets Title 14 Code of Federal Regulations (CFR), part 21, subpart K. The Federal Aviation Administration (FAA) approves the submitted data. The FAA reserves the right to require changes, additions, or clarifications that may become necessary as a result of subsequent inspections and/or evaluations.

This notification should remain on file as evidence of FAA review of your Quality Control System document.

Document Name: Quality Management System Manual

Document Number: 512-0000-000-000

Revision Number: AB

Date: April 27, 2016

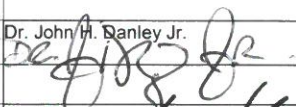


Sincerely,

Joedy Collado  
Principal Inspector

LTR	DESCRIPTION	DATE	APPROVED
A	Formal release per EO 06795	6/8/87	P. Contreras
B	Rewritten per EO 08158	7/14/88	V. Santos
C	Rewritten per EO 060619	12/14/95	J. Gray
D	Rewritten per EO 062809	11/25/96	K. Paterson
E	Rewritten per EO 063792	4/23/97	K. Paterson
F	Rewritten per EO 063868	5/1/97	K. Paterson
G	Rewritten per EO 064129	6/10/97	E. Kolesar
H	Rewritten per EO 064267	6/24/97	K. Paterson
J	Rewritten per EO 064608	8/27/97	K. Paterson
K	Rewritten per EO 064782	8/28/97	K. Paterson
M	Rewritten per EO 065107	10/14/97	K. Paterson
N	Rewritten per EO 065380	11/17/97	K. Paterson
P	Rewritten per EO 67257	9/1/98	K. Paterson
R	Removed from Engineering Services Document Control	10/12/01	J. Gray
T	Rewritten into compliance with AS9100:2001	9/9/03	J. Gray
U	Revised to address audit findings	11/21/03	J. Gray
V	Revised to add narrative description of process interaction	2/21/05	J. Gray
W	Rewritten per DCN 0090	08/07/09	M. Segari
X	Rewritten per DCN 0191	07/29/11	J. Gray
Y	Revised to DCN 0305	06/14/12	J. Gray
Z	DCN 0488	9/25/14	ML
AA	DCN 0697	11/25/15	J. Danley
AB	DCN 0865	4/27/16	J. Brooks

## QUALITY MANAGEMENT SYSTEM MANUAL

This Document is "**Control-On-Use**" and should not be used unless the user has verified that this document is current. Current documents are available on the QMS SharePoint database. Este Documento "**Controlados-En-Uso**" y no será utilizado al menos que el usuario haya verificado que éste documento sea el más actual. Los documentos más actuales están disponibles en la red en QMS SharePoint databas.

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Unit President EPS N.A.	Dr. John H. Danley Jr. 	<b>QUALITY MANAGEMENT SYSTEM MANUAL</b>
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QMS	Maria Langley 	<b>DOC. NO. 512-0000-000-000</b>
		<b>REV. AB</b>
		<b>4/27/16</b>
		<b>SHEET 1 OF 24</b>

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## 1.0 SCOPE

The Quality Management System (QMS) manual provides a single standard applicable to commercial and military contracts that meets below requirements. This document summarizes the process approach based Quality Management System at LINA and identifies all associated Quality Management System documentation. Established procedures used by Leach International - North America (LINA) for the implementation and maintenance of an effective, efficient and economical Quality Management System to promote enhanced customer satisfaction through compliance to contractual, statutory and regulatory requirements:

- In compliance with the latest version of SAE AS9100
- Our QMS system will incorporate QAP 9.0 procedures and processes focusing on our Trade Compliance Program. QAP 9.0 is a procedure outlining our Trade Compliance Program. The program is inclusive of procedures that extend across our functional business in both Buena Park, CA and our facility in Tijuana, MEX.
- In compliance with the reporting and configuration control requirements of MIL-STD-790 for established Reliability military specification product.
- In compliance with FAR Subpart K-Parts Manufacturer Approvals, FAR 21.137, FAR 21.3, FAR 45.15, FAR 21 Subpart L-Export Airworthiness Approval and FAR 21.502 Acceptance of articles under FAR 21 Subpart N-Acceptance of aircraft engines, propellers, and articles for import if applicable in accordance with the requirements for Parts Manufacturer Approval.
- In compliance with FAR 145 and EASA.145.5169 in accordance with the requirements for operating an FAA and EASA approved domestic Repair Station.
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This manual requires that all products and/or services meet all requirements established by the customer, in the individual contract or purchase order, as a minimum. Other Quality System requirements imposed by applicable Regulatory Authorities are included or referenced in the Quality System documentation. It assures that Quality Assurance requirements are determined and satisfied throughout all phases of contract performance, and provides for early detection and correction of deficiencies, trends or conditions that could result in unsatisfactory performance.

### 1.1 GENERAL

This manual outlines the practices of LINA relating to its Quality Management System. This manual provides comprehensive evidence to all customers, suppliers, and employees that LINA is committed to establishing and maintaining acceptable levels of measurable Quality in its products and services to meet customer and applicable statutory and regulatory requirements, and to enhance customer satisfaction through continual improvement and prevention of nonconformity.

### 1.2 APPLICATION

This Quality Management System manual applies to all activities and personnel within LINA in Buena Park and Leach International – Mexico (LIMEX). Exclusions in LIMEX include: Customer Related Process, Program Management, and Design & Development.

### 1.3 AUTHORITY

This manual is issued under the authority of the President of Leach International North America. ***The President is the Accountable Manager as defined in Part 21.305 (3)(b). The Accountable Manager is the primary point of contact to the FAA and may delegate that function as required. This however does not relieve the President of this responsibility.***

### 1.4 ISSUE OF THE MANUAL

The Quality System Manual is maintained on company intranet at <http://linanet/Department/Quality Assurance> and a copy of the manual is also available at [www.leachintl.com](http://www.leachintl.com) (see Quality Assurance

under the Product headers). The Quality System Manual is issued, controlled and maintained by LINA Quality Systems function.

#### 1.5 AMENDMENT

Controlled manuals are updated and revised as required. The issue of amendments requires approval by local FAA MIDO and the President and the Director of Quality Assurance.

## 2.0 **APPLICABLE DOCUMENTS**

The following documents, of the issue contractually invoked, form a part of this document to the extent specified herein.

- FAR 21 Certification procedure for products and parts; FAR 45 Identification and Registration Marking
- MIL-STD-790 Product Assurance System for Electronic and Fiber Optic Parts Specifications
- SAE AS9100 Quality Management Systems – Aerospace - Requirements
- SAE AS9102 First Article Inspection, SAE AS9103 Variation Management of Key Characteristics
- ISO 10007 Quality Management Systems – Guidelines for configuration management
- QAP 9.0

## 3.0 **TERMS AND DEFINITIONS**

The terms and definitions given in AS9100 section 3 Terms and Definitions apply.

## 4.0 **QUALITY MANAGEMENT SYSTEM**

### 4.1 General Requirements

LINA has established, documented and implemented and maintains a Quality Management system and continually improve its effectiveness in accordance with the requirements of ISO 9001 International Standard, AS9100 Aerospace Standard, PAH and rules and other imposed requirements. The organization's quality management system is also address customer and applicable statutory and regulatory quality management system requirements.

Leach International has;

- a. Determined the processes needed for the quality management system and their application throughout the organization,
- b. Determined the sequence and interaction of these processes,
- c. Determined criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d. Ensured the availability of resources and information necessary to support the operation and monitoring of these processes,
- e. Monitored, measured where applicable, and analyzed these processes, and
- f. Implemented actions necessary to achieve planned results and continual improvement of these processes.

These processes are managed by Leach International in accordance with the requirements of ISO9001 International Standard and AS9100 Aerospace Standard and our Trade Compliance Program.

Leach International Process-Based Management Model is illustrated in Figure 1. The sequences and interaction among identified processes needed for the quality management system and their application throughout the organization. Key processes are designated in "Yellow".

When Leach International chooses to outsource any process that affects product conformity to requirements, Leach International ensures control over such processes. The type and extent of control applied to these outsourced processes have been defined within the quality management system.

Note 1: Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.

Note 2: An “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

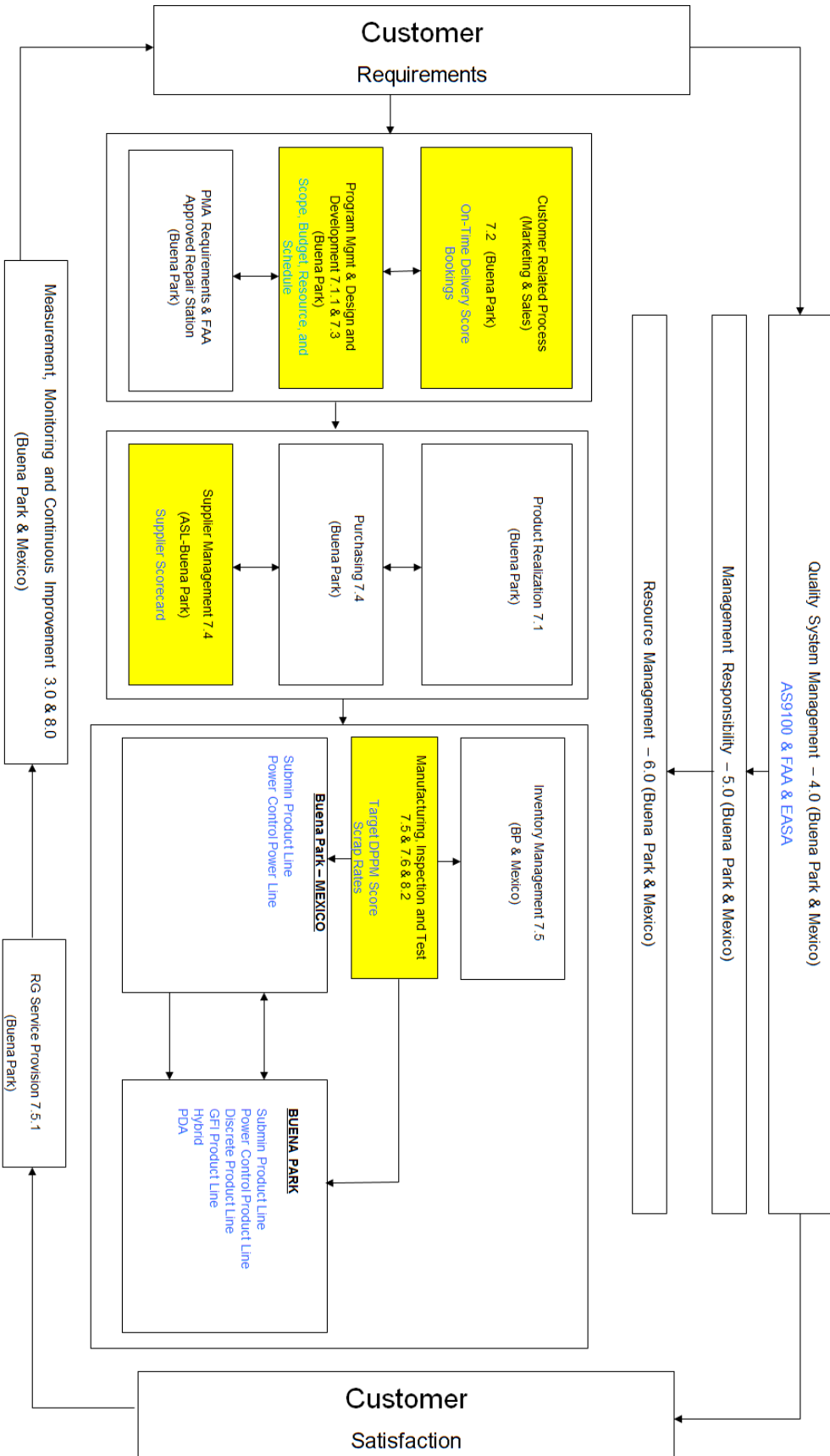
Note 3: Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customers, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

- a) The potential impact of the outsourced process on the organization’s capability to provide product that conforms to requirements.
- b) The degree to which the control for the process is shared.
- c) The capability of achieving the necessary control through the application 7.4.

Leach International allows FAA to inspect;

- Its quality system, facilities, technical data, and any manufactured products or articles; and
- Have access to design data necessary to determine conformity and airworthiness for each article produced under the PMA.
- Witness any tests including any inspections or tests at any supplier facility (within the Leach International’s supply chain) necessary to determine compliance with the applicable subchapter.
- Unless otherwise authorized by the FAA,
  - Leach may not present any article to the FAA for an inspection or test unless compliance with 21.303 (b) (2) through (4) has been shown for that article, and
  - May not make any change to an article between the time that compliance with 21.303(b) (2) through (4) is shown for that article and the time that the article is presented to the FAA for the inspection or test.
- Leach International ensures FAA access to, and cooperation of, all involved facilities in its supply chain. Also ensures access to and cooperation of all involved facilities in the supply chain for Leach International or their representatives.

# Leach International Process-Based Management Model



to ensure the  
levant quality

management system documentation and are aware of relevant procedures and changes. Customer and/or regulatory authorities' representatives are given access to Quality Management System documentation as required by contract or regulation.

#### 4.2.2 Quality Manual

LINA has established and maintains this document, 512-0000-000-000, "Quality Management System Manual", as the quality manual that documents all the requirements of the Quality Management System. It provides the scope of the Quality Management System, including details of and justification for any exclusions (see 1.2), QAD 00043 clearly illustrates the relationship between Leach Quality System procedures, the requirements of AS9100/ISO standards and FAA PMA requirements), and a description of the interaction between the processes of the Quality Management System. The manual must be in English language and retrievable in a form acceptable to the FAA. The Quality Management System will include QAP 9.0.

#### 4.2.3 Control of Documents

All Quality-System related documents are available from the Local Area Network (LAN). All quality system documents are "Control-on-Use" and should not be used unless the user has verified that this document is current as on the network.

- a) Quality Systems Documents, including QAM, QAD, QAP, QAI and QAF, are controlled by Quality Systems Function according to QAP 1.4 Quality Management System Document Control.
- b) Other Quality System Documents and Product Quality Assurance Documents controlled by Engineering Service Functions according to QAP 2.1 Engineering Documentation Control.

All above documented procedures have been established to define the controls needed;

- a) To approve documents for adequacy prior to issue,
- b) To review and update as necessary and re-approve documents,
- c) To ensure that changes and the current revision status of documents are identified,
- d) To ensure that relevant versions of applicable documents are available at points of use,
- e) To ensure that documents remain legible and readily identifiable,
- f) To ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
- g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Leach has established procedure to coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

#### 4.2.4 Control of Records

Documented procedures with records are established and controlled to provide evidence of conformity to requirements and of the effective operation of the quality management system. It is to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. Records shall remain legible, readily identifiable and retrievable.

Documented procedures are established to define the method for controlling records that are created by and/or retained by suppliers.

Records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

## 5.0 **MANAGEMENT RESPONSIBILITY**

### 5.1 **MANAGEMENT COMMITMENT**

Top management of LINA demonstrates its commitment to the development and implementation of the



Quality Management System and the continual improvement of its effectiveness by: communicating to all employees importance of meeting customer as well as statutory and regulatory requirements; establishing the Quality Policy (see paragraph 5.3); ensuring that quality objectives are established (see paragraph 5.4.1); conducting management reviews (see paragraph 5.6); ensuring the availability of resources (see paragraph 6.1).

## 5.2 CUSTOMER FOCUS

The management of LINA ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see paragraphs 7.2.1 and 8.2.1).

Top management of LINA shall ensure that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not, or will not be achieved.

## 5.3 QUALITY POLICY

The management of LINA ensures that the quality policy is appropriate to the purpose of LINA, includes a commitment to comply with requirements and continually improve the effectiveness of the Quality Management System, provides a framework for establishing and reviewing customer satisfaction objectives, is communicated and understood within LINA, and is reviewed for continuing suitability.

## 5.4 PLANNING

### 5.4.1 Quality Objectives

Top management ensures that quality objectives, including those needed to meet requirements for product (see 7.1), are established at relevant functions and levels within LINA. The quality objectives are measurable and consistent with the quality policy.

### 5.4.2 Quality Management System Planning

Top management ensures that the planning of the Quality Management System is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and the integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented.

## 5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

### 5.5.1 Responsibility and Authority

Top management has ensured that the responsibilities and authorities are defined and communicated within LINA through documented procedure.

### 5.5.2 Management Representative

Leach International's President has appointed the Quality Assurance department head as the management representative responsible for the Quality Management System. The Quality Assurance department head is delegated authority for assuring that the processes needed for the Quality Management System are established, implemented, and maintained in accordance with the applicable requirements. This includes responsibilities for;

- Monitoring conformance to the program requirements,
- Reporting to top management on the performance of the Quality Management System and any need for improvement,
- Ensuring the promotion of awareness of customer requirements throughout LINA.
- Ensuring that where applicable that each Org has desk Top Procedures for our Trade Right Program.

The Management Representative reports directly to the President to assure the necessary authority, unrestricted access to top management and organizational freedom to resolve quality management issues. Changes in delegation are reported as required by contract or regulation.

### 5.5.3 Internal Communication

Top management ensures that appropriate communication processes are established within LINA and that communication takes place regarding the effectiveness of the Quality Management System. This communication system includes, but is not limited to, departmental activity reports, training records and training due date reports, design review records, corrective action records, audit records, quality improvement team reports, records of monitoring and measuring of processes, customer feedback, customer satisfaction, and minutes of management reviews.

## 5.6 MANAGEMENT REVIEW

### 5.6.1 General

Top management schedules and holds Quality Management System reviews on regularly scheduled basis to ensure the quality management system continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. The Head of Quality Assurance shall be responsible for the coordination of management review activity per QAP 1.7. Records from management reviews are maintained according to QAP 2.3 Record Retention.

### 5.6.1 Review Input: The input to management review includes information on

- a) Results of audits,
- b) Customer feedback,
- c) Process performance and product conformity,
- d) Status of preventive and corrective actions,
- e) Follow-up actions from previous management reviews,
- f) Changes that could affect the quality management system, and
- g) Recommendations for improvement.

### 5.6.3 Review Output: The output from the management review shall include any decisions and actions related to

- a) Improvement of the effectiveness of the quality management system and its processes,
- b) Improvement of product related to customer requirements, and
- c) Resource needs.

## 6.0 RESOURCE MANAGEMENT

### 6.1 PROVISION OF RESOURCES

LINA determines and provides the resources needed to implement and maintain the Quality Management System and continually improve its effectiveness, and to enhance customer satisfaction by meeting customer requirements.

### 6.2 HUMAN RESOURCES

#### 6.2.1 General

Management assures that personnel performing work affecting conformity to product requirements are competent on the basis of appropriate education, training, skills and experience.

#### 6.2.2 Competence, Awareness and Training

LINA determines the necessary competence for personnel performing work affecting conformity to product requirements, where applicable, provides training or takes other actions to achieve the necessary competence, evaluates the effectiveness of the actions taken, ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and maintains appropriate records of education, training, skills and experience (see 4.2.4). For FAA-Approved Repair station training requirements, Leach International shall follow FAA-Approved 512-0006-003-000 Repair Station Training Program Manual.

### 6.3 INFRASTRUCTURE

LINA management determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable, buildings, workspace and associated utilities; process equipment (both hardware and software); and supporting services (such as transport or communication or information systems). Utilities and supplies such as water, compressed air, electricity, and chemical products are controlled to the extent they affect product quality.

### 6.4 WORK ENVIRONMENT

LINA management determines and manages the work environment needed to achieve conformity to product requirements. Procedures are established and maintained to assure all manufacturing and inspection operations are performed in an environment (e.g., the term "work environment" relates to those conditions under which work is performed including physical, environmental and other factors such as noise, temperature, humidity, lighting or weather.) that is consistent with the end application and critical nature of the article.

## 7.0 PRODUCT REALIZATION

### 7.1 PLANNING OF PRODUCT REALIZATION

LINA plans and develops the processes needed for product realization. The planning of product realization is consistent with the requirements of the other processes of the Quality Management System (see 4.1). In planning product realization, LINA determines the following, as appropriate:

- a) quality objectives and requirements for the product;
- b) the need to establish processes and documents, and to provide resources specific to the product;

- c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
- d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4);
- e) configuration management appropriate to the product;
- f) Identification of resources to support the use and maintenance of the product;

The output of this planning is in a form suitable for Leach International's method of operations.

The preparation of quality plans are processed through the contract review process (existing products and variants) or a design review process (new products).

Leach International applies the requirements given in 7.3 to the development of product realization processes.

#### 7.1.1 Project Management

As appropriate to the organization and the product, the organization shall plan and manage product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints.

#### 7.1.2 Risk Management

The process has been established, implemented and maintained at LINA for managing risk to the achievement of applicable requirements, that includes as appropriate to the organization and the product;

- a. assignment of responsibilities for risk management,
- b. definition of risk criteria (e.g., likelihood, consequences, risk acceptance),
- c. identification, assessment and communication of risks throughout product realization,
- d. identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and
- e. acceptance of risks remaining after implementation of mitigation actions.

#### 7.1.3 Configuration Management

The configuration management process has been established, implemented and maintained that includes, as appropriate to the product;

- a. configuration management planning,
- b. configuration identification,
- c. change control,
- d. configuration status accounting, and
- e. configuration audit.

#### 7.1.4 Control of Work Transfers

Leach has established, implemented and maintains a process to plan and control the temporary or permanent transfer of work (e.g., from one organization facility to another, from the organization to a supplier, from one supplier to another supplier) and to verify the conformity of the work to requirements.

When temporarily or permanently planning to carry out work at a location other than its normal facilities, the procedure to control and validate quality of the work is defined.

## 7.2 CUSTOMER-RELATED PROCESSES

### 7.2.1 Determination of Requirements Related to the Product

Documented procedures are established and maintained defining the contract and tender review processes. LINA determines the requirements specified by the customer, including the requirements for delivery and post delivery activities, the requirements not stated by the customer but necessary for specified or intended use, where known, the statutory and regulatory requirements applicable to the product, and any additional requirements considered necessary and determined by LINA.

### 7.2.2 Review of Requirements Related to the Product

Leach International has a process in place for the review of requirements related to the product. The review is conducted before the order is accepted. Verbal orders are documented by the receiving party and subjected to identical review. The process ensures that;

- Product/contractual requirements are defined. Contract or order requirements differing from those previously expressed are resolved
- Leach International has the ability to meet the defined requirements
- Special requirements of the product are determined, and
- Records are maintained showing the result of the review and any actions arising from the review.
- When the product requirements are changed, Leach International communicates changes to relevant personnel and amends relevant documents.
- Leach identifies and evaluates the risk associated with new technology or short delivery time scale.

### 7.2.3 Customer Communication

LINA has determined and implemented effective arrangements for communicating with customers in relation to product information, enquiries, contracts or order handling, including amendments, and customer feedback, including customer complaints.

## 7.3 DESIGN AND DEVELOPMENT

Documented procedures are established and maintained to, plan, control and verify the design of product to assure compliance to design control requirements and quality criteria during the development and pre-production stages. When a subcontractor performs design or development activities, the subcontracted activity is controlled consistent with the requirements of section 7.3.

### 7.3.1 Design and Development Planning

The design and development procedure outlines the process for controlling the design and development process. The Engineering Department plans design and development according to this procedure. The design plan includes:

- Design and development stages including organization, task sequence, mandatory steps, significant stages, and method of configuration control.
- Required design reviews, verification and validation appropriate to each design and development stage.
- Responsibilities and authorities for design and development.

Where appropriate, due to complexity, Leach International gives consideration to the following activities:

- o Divide the design and development effort into distinct activities;
- o For each activity, define the tasks, necessary resources, responsibilities, design content, input and output data and planning constraints;

The different design and development tasks to be carried out shall be based on safety and functional objectives of the product in accordance with customer, statutory and regulatory requirements.

Design and development planning shall consider the ability to produce, inspect, test and maintain the product.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

7.3.2 Design and Development Inputs: Input relating to product requirements are determined and records maintained (see 4.2.4). These inputs shall include;

- a) functional and performance requirements,
- b) applicable statutory and regulatory requirements,
- c) where applicable, information derived from previous similar design, and
- d) other requirements essential for design and development.

These inputs are reviewed for adequacy. The design control procedure assures the proper identification, documentation, and review of design input and statutory/regulatory requirements to assure adequate definition so that incomplete, ambiguous, or conflicting requirements are resolved with those imposing the requirements.

7.3.1 Design and Development Outputs: The outputs of design and development are provided in a form suitable for verification against the design and development input and need to be approved prior to release. Design and development outputs shall

- a) Meet the input requirements for design and development,
- b) Provide appropriate information for purchasing, production and for service provision,
- c) Contain or reference product acceptance criteria,
- d) Specify, as applicable any critical items, the characteristics of the product that are essential for its safe and proper use, and;
- e) Identify key characteristics, when applicable, in accordance with design or contract requirements.

All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained require to be defined by Leach International; such as, but not limited to

- Drawings, part lists, specifications;
- A list of those drawings, part lists, and specifications necessary to define the configuration and the design features of the product;
- Information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product.

7.3.4 Design and Development Review

The design control procedure assures that at appropriate stages of design, formal documented design reviews are planned and conducted in accordance with planned arrangements (see

7.3.1), and include representatives of all functions concerned with the design stage being reviewed, as well as other specialist personnel, as required. The review includes verification of configuration and process change control provisions to assure configuration management is maintained where contractually imposed. Records of such reviews and any necessary actions are maintained (see 4.2.4). The design control procedure assures that consideration is given to the validity of design in relation to the objectives of the design stage, actions to be taken in the event of any identified deviation, and authorized decision necessary for progression to the next stage.

#### 7.3.5 Design and Development Verification

The design control procedure assures that at appropriate stages of design, design verification is conducted in accordance with planned arrangements (see 7.3.1) to assure the design stage output meets the design stage input requirements. Design and/or development verification may include activities such as performing alternative calculations; comparing the new design with a similar proven design, if available; undertaking tests and demonstrations; and reviewing the design stage documents before release. Records of design verification and any necessary actions are maintained. Where required to demonstrate product qualification, records are maintained to provide evidence that the product meets the defined requirements.

#### 7.3.6 Design and Development Validation

The design control procedure assures that design validation is performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Validation may be performed by analysis where similar product has proven performance. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained (see 4.2.4).

##### 7.3.6.1 Design and Development Verification and Validation Testing

Where tests are necessary for verification and validation, these tests are planned, controlled, reviewed and documented to ensure and prove the following

- a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria,
- b) test procedures describe the method of operation, the performance of the test and the recording of the results,
- c) the correct configuration of the product is submitted for the test,
- d) the requirements of the test plan and test procedures are observed, and
- e) the acceptance criteria are met.

##### 7.3.6.2 Design and Development Verification and Validation Documentation

At the completion of design and/or development, the organization shall ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions.

#### 7.3.7 Control of Design and Development Changes

The design control procedure assures all design changes and modifications are identified and records are maintained. The changes are documented, reviewed, verified and validated, as appropriate, and approved by authorized personnel prior to implementation. The review of design and development changes includes evaluation of the effect of the changes on constituent parts and product already delivered. For PMA, the design data and subsequent changes shall be controlled to ensure that only current, correct, and approved data is used. The design control

procedure assures to provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement. Records of the results of the review of changes and any necessary actions are maintained (see 4.2.4).

Design and development changes shall be controlled in accordance with the configuration management process (see 7.1.3).

## 7.4 PURCHASING

### 7.4.1 Purchasing Process

Documented procedures are established and maintained to assure that all purchased product conforms to the requirements. Procurement sources are evaluated and controlled to assure an adequate quality system exists, that all workmanship standards, materials and services conform to the requirements of the governing documents, and suppliers are notified of all applicable requirements.

When required by contract, customer designated suppliers/processors are utilized, however Leach remains responsible for assuring the conformity of all purchased goods and services.

Leach International evaluates and selects suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation are established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained (see 4.2.4).

Leach International shall:

- a) Maintain a register of its suppliers that includes approval status and the scope of the approval;
- b) Periodically review supplier performance; records and results of these reviews shall be used as a basis for establishing the level of controls to be implemented;
- c) Define the necessary actions to take when dealing with suppliers that do not meet requirements;
- d) Ensure where required that both the organization and all suppliers use customer-approved special process sources;
- e) Define the process, responsibilities and authority for the approval status decision, change of the approval status and conditions for a controlled use of suppliers depending on the supplier's approval status and
- f) Determine and manage the risk when selecting and using suppliers (see 7.1.2).

### 7.4.2 Purchasing Information

All purchase orders and subcontracts contain data clearly describing the product or service ordered, including where applicable:

- a) Requirements for approval of product, procedures, processes and equipment,
- b) Requirements for qualification of personnel,
- c) Quality management system requirements,
- d) The identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data,
- e) Requirements for design, test, examination, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by Leach International and as applicable critical items including key characteristics,
- f) Requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing,
- g) Requirements relative to supplier notification to Leach International of nonconforming product and obtain Leach International approval for nonconforming product



- disposition,
- h) Requirements for the supplier to notify Leach International of changes in product and/or process definition and, where required, obtain Leach International approval and/or further regulatory and/or customer approval. Changes of suppliers, changes of manufacturing facility location and where required, obtain Leach International's approval and flow down to the supply chain the applicable requirements including customer requirements.
  - i) Records retention requirements and
  - j) Right of access by Leach International, their customer(s), and regulatory authorities to the applicable areas of all facilities, at any level of supply chain, involved in the order and to all applicable records.

Supplier Management reviews and approves purchasing documents for adequacy of the specified requirements prior to their communication to the supplier. Quality Assurance monitors purchase orders, to assure incorporation of the same.

#### 7.4.3 Verification of Purchased Product

Verification of purchased product is accomplished either upon receipt by obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control) and reviewing the required documentation, or by inspection of the products upon receipt. Purchased product can also be verified at the supplier's facility by source inspection, through delegation of verification to the supplier, or supplier certification. Verification activities includes,

- a) Obtaining objective evidence of the quality of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control),
- b) Inspection and audit at supplier's premises,
- c) Review of the required documentation,
- d) Inspection of product upon receipt, and (for PMA, supplier-furnished product or article conforms to its approved design)
- e) Delegation of verification to the supplier, or supplier certification.

Leach International utilizes following methods to ensure the compliance:

- a) Supplier Provided Evidence,
- b) Inspection on Receipt,
- c) Raw Material Verification,
- d) Urgent Material Release
- e) Identification and Storage,
- f) Leach Source Inspection,
- g) Customer Source Inspection,
- h) Delegation of Product Verification

Right of Entry - Leach includes provisions in supplier purchasing documents to allow Leach, its customers, and regulatory agencies access to verify records, materials, and quality of work at any location.

Requirements Flow-down - Quality system requirements are flowed down to suppliers to the extent necessary to assure that characteristics not verifiable upon receipt are adequately controlled by the supplier.

Verification by the customer shall not be used by Leach International as evidence of effective control of quality by the supplier and shall not absolve the organization of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

When purchased product is released for production use pending completion of all required verification activities, it will be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

When Leach International delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.

Where Leach International or its customer intends to perform verification at the supplier's premises, Leach International shall state the intended verification arrangements and method of product release in the purchasing information.

## 7.5 PRODUCTION AND SERVICE PROVISION

### 7.5.1 Control of Production and Service Provision

Planning considers, as applicable, the establishment of process controls and development of control plans where key characteristics have been identified, the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization, the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and special processes (see 7.5.2).

LINA plans and carries out production and service provision under controlled conditions. Controlled conditions include, as applicable:

- a. the availability of information that describes the characteristics of the product,  
Documented procedures are established and maintained to control all documents and data that relate to the Quality Management System, including to the extent applicable, documents of external origin such as standards and customer drawings used directly in the manufacture of product. This data contains, as necessary, drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards), inspection documents (see 8.2.4.1),
- b. the availability of work instructions, as necessary,  
There is a list of specific or non-specific tools and numerical control (NC) machine programs required and any specific instructions associated with their use.
- c. the use of suitable equipment,
- d. the availability and use of monitoring and measuring devices,
- e. the implementation of monitoring and measurement,
- f. the implementation of release, delivery and post-delivery activities,
- g. accountability for all product during production (e.g., parts quantities, split orders, nonconforming product),
- h. evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized,
- i. provision for the prevention, detection, and removal of foreign objects,
- j. monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect the conformity to product requirements, and
- k. criteria for workmanship, which is stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations).

Planning shall consider, as appropriate

- Establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified.
- Designing, manufacturing and using tooling to measure variable data,
- Identifying in-process inspection/verification points when adequate verification of conformance can not be performed at later stages of realization, and

- Special processes (see 7.5.2).

#### 7.5.1.1 Production Process Verification

Documented procedure are established and maintained to use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This process is required to be repeated when changes occur that invalidate the original results such as engineering changes, manufacturing process changes, tooling changes and etc. Leach International shall follow guidance of SAE AS 9102.

#### 7.5.1.2 Control of Production Process Changes

Authorized people for approving changes to product processes are identified in the documented procedures. Leach International identifies and obtains acceptance of changes that require customer or regulatory authority approval in accordance with contract or regulatory requirements. Changes affecting processes, product equipment, tools and software programs are documented and controlled procedures are available to control the implementation of changes.

The results of changes to production processes are assessed to confirm that the desired effect has been achieved without advert effects to product conformity.

#### 7.5.1.3 Control of Production Equipment, Control of Production Equipment, Tools and Numerical Control (N.C.) Machine Programs

Production equipment, tools and software programs used to automate and control/monitor production realization processes are validated prior to release for production and the records shall be maintained and inspected periodically according to documented procedures. Validation prior to production use includes verification of the first article produced to the design data/specification. Production equipment or tooling storage requirements, including periodic preservation/condition checks, have been be established for production equipment or tooling in storage.

#### 7.5.1.4 Post-Delivery Support

A Material Service Center (MSC), responsible for the management of all returned goods, has established and is maintained. The Material Service Center operations manual documents all MSC activities and assures compliance with all Leach, customer, and regulatory agency requirements. Where servicing is specified requirement, service operation processes shall provide for

- a) Collection and analysis of in-service data. Documented procedures for receiving and processing feedback on in-service failure, malfunctions, and defects.
- b) Actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements, specific FAA Repair Station activities (for parts listed on 512-0006-001-000 Capability List) shall follow FAA Approved Repair Station Manual 512-0006-000-000.
- c) The control and updating of technical documentation,
- d) The approval, control and use of repair schemes. Overhaul and repair procedures 512-0006-002-000 are in compliance with current Federal Aviation Requirements (FAR) and Leach policy.
- e) The controls required for off-site work. Controls for off-site work will be developed if offsite work becomes a requirement in the future.

#### 7.5.2 Validation of Processes for Production and Service Provision

Leach International validates any processes for production and service provision where the resulting output can not be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planning results.

Leach International has documented the process for validation including:

- Defined criteria for review and approval of the processes
- Approval of equipment and qualification of personnel,
- Use of specific methods and procedures.
- Requirements for records, and
- Revalidation

#### 7.5.3 Identification and Traceability

Documented procedures are established and maintained to identify product undergoing fabrication or assembly from receipt and during all stages of production throughout product realization and delivery to the extent required by contract. Product status is identified with respect to monitoring and measurement requirements. A procedure establishes and controls acceptance authority media used (e.g., stamps, electronic signatures, passwords). When specified by requirement, the procedures allow for unique identification of individual product or batches for traceability, which is recorded (see 4.2.4). When traceability is required, loss of traceability is considered a nonconformance.

When required by contract, regulatory or other established requirement, provisions are made for identification to be maintained throughout the product life, for traceability of all product manufactured from the same batch of raw material or from the same manufacturing batch to destination (delivery, scrap, etc.), for an assembly, the ability to trace to its components and to the next higher assembly, for retrieval of the sequential production record (manufacture, assembly, inspection/verification) of a given product, and for maintenance of identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration. Materials or items having characteristics of degradation with age are marked and controlled to prevent use beyond their useful life. Provisions for records of this identification are included.

#### 7.5.4 Customer Property

General - Customer/Government Furnished Property (CFP/GFP) is used to identify any material, tools or gauges supplied to Leach International by a customer or the government, for use in the performance of a specific contract or series of contracts. Customer property can include intellectual property, including customer furnished data used for design, production and/or inspection. Documented procedures are established and maintained to assure proper control of CFP/GFP. Care is exercised with CFP/GFP while it is under the LINA's control or being used by the LINA. LINA identifies, verifies, protects and safeguards CFP/GFP provided for use or incorporation into the product. If any CFP/GFP is lost, damaged or otherwise found to be unsuitable for use, it is reported to the customer/government and records maintained (see 4.2.4).

#### 7.5.5 Preservation of Product

Leach International preserves the conformity of product during internal processing and delivery to the intended destination according to defined procedure in order to maintain conformity to requirements. As applicable, this preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

The organization ensures that documents required by the contract or order to accompany the product is present at the delivery and is protected against loss and deterioration. Preservation of production shall include, where applicable in accordance with product specifications and applicable statutory and regulatory requirements, provisions for

- a. cleaning,
- b. prevention, detection and removal of foreign objects,
- c. special handling for sensitive products,
- d. marking and labeling including safety warnings,
- e. shelf life control and stock rotation, and
- f. special handling for hazardous materials.

## 7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENTS

Leach international has determined the monitoring and measurement to be undertaken and the monitoring and measuring equipments needed to provide evidence of conformity of product to determined requirements. A documented procedure outlines the process used to ensure that monitoring and measurement to be carried out are carried out in a manner that is consistent with the monitoring and measurement requirements.

- Calibrated and verified, or both, at specified 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 result
- Protected from damage and deterioration during handling, maintenance and storage
- Established process in place to establish, implement and maintain for the recall of monitoring measuring equipment requiring calibration or verification.

In addition, Quality Assurance assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements.

Leach International takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained.

Leach International maintains a register of these monitoring and measuring equipments.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This is undertaken prior to initial use and reconfirmed as necessary.

Leach International ensures that environmental conditions are suitable for the calibration, inspections, measurements and tests being carried out.

## 8.0 **MEASUREMENT, ANALYSIS AND IMPROVEMENT**

### 8.1 GENERAL

Leach International plans and implements the monitoring, measurement, analysis and improvement processes as needed

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

These processes are identified in documented procedures and include consideration and determination of applicable methods, including statistical techniques such as statistical sampling, SPC, control charts and gage variability study, DOE, inspection, and failure mode, effect and criticality analysis and etc., and the extent of their use.

## 8.2 MONITORING AND MEASUREMENT

### 8.2.1 Customer Satisfaction

One measure of the performance of the Quality Management System is the monitoring of information relating to the customer perception as to whether LINA has met customer requirements through supplier performance scorecard and customer on-site audits.

Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product conformity, on-time delivery performance, customer complaints and corrective action requests. Leach develops and implements plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

### 8.2.2 Internal Audit

General - LINA conducts internal audits at planned intervals to determine whether the Quality Management System conforms to the planned arrangements (see 7.1), to the requirements of the applicable National and International Standards, and to the Quality Management System requirements established by LINA; and is effectively implemented and maintained. Internal audits are planned to also meet contract and/or regulatory requirements.

The audit program planning takes into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. Audits include examination of all quality operations and documentation. The audit criteria, scope, and methods are defined and the selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process.

Trained, knowledgeable personnel independent of those having direct responsibility of the activity being audited perform audits and auditors are not allowed to audit their own work. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) are defined per QAP 1.9 . Audits are performed to detailed check-sheets when contractually required. When check-sheets are not used, process flowcharts, detailed travelers, actual documents or other media can be used to record the audit process. The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall organization performance.

### 8.2.3 Monitoring and Measurement of Processes

Suitable methods are used for monitoring and, where applicable, measurement of the Quality Management System processes to demonstrate the ability of the processes to achieve planned results.

These methods should as a minimum include:

- a) reviews of the quality objectives (5.4.1) as part of management reviews (5.6),
- b) of the internal audits (8.2.2),
- c) of customer satisfaction (8.2.1),
- d) of analysis of data (8.4),
- e) of nonconforming product (8.3).

When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product (control of nonconforming product per 8.3 and corrective and preventive action per 8.5.2 and 8.5.3), or through the continual improvement program (8.5.1). When planned results are not achieved due to process nonconformities, appropriate action is taken to correct the nonconforming process, to evaluate whether the process nonconformity has resulted in product nonconformity, to determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and non and to identify and control any nonconforming product in accordance with paragraph 8.3.

### 8.2.4 Monitoring and Measurement of Product

Monitoring and measurement of the characteristics of the product to verify that product requirements have been met are carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

Measurement requirements for product or service acceptance are documented. This documentation may be part of the production documentation, but includes criteria for acceptance and/or rejection, where in the sequence measurement and testing operations are performed, a record of the measurement results, and type of measurement instruments required and any specific instructions associated with their use. Test records show actual test results data when required by specification or acceptance test plan. Where required to demonstrate product qualification LINA ensures that records provide evidence that the product meets the defined requirements.

- Criteria for acceptance and/or rejection,
- Where in the sequence measurement and testing operations are performed,
- A required records of the measurement results (at a minimum, indication of acceptance or rejection), and
- Any specific measurement instruments required and any specific instructions associated with their use.

Any characteristics identified as critical items, including key characteristics are monitored and controlled in accordance with the established process.

The plans for sampling inspections used as a means of product acceptance are justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).

Where product is released for production use pending completion of all required measurement and monitoring activities, it will be identified and recorded to allow recall and replacement if it is

subsequently found that the product does not meet requirements.

Leach shall ensure that each PMA article conforms to its approved design and is in a condition for safe operation.

Evidence of conformity with the acceptance criteria is maintained and records indicate the person(s) authorizing release of product (see 4.2.4).

Where required to demonstrate product qualification, Leach ensures that records provide evidence that the product meets the defined requirements.

Product release and service delivery are not allowed to proceed until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved, where applicable by regulatory authorities and/or by the customer. Established procedure ensures that all documents required to accompany the product are present at delivery.

### 8.3 CONTROL OF NONCONFORMING PRODUCT

Leach International has established procedure in place to;

- a. take action to eliminate the detected nonconformity;
- b. by authorize its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- c. take action to preclude its original intended use or application;
- d. take action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

The controls and related responsibilities and authorities for dealing with nonconforming product are defined in the Control of Nonconforming Product Procedure QAP 6.1. The term “nonconforming product” includes nonconforming product returned from a customer.

Dispositions of use-as-is or repair shall only be used after approval by an authorized representative of the organization responsible for design. The organization does not use dispositions of use-as-is or repair, unless specifically authorized by the customers, if:

- The product is produced to customer design, or
- The nonconformity results in departure from the contract requirements.

Unless otherwise restricted by contract, Leach International designed product that is controlled by a customer specification may be disposition by Leach International as use-as-is or repair provided the nonconformity does not result in a departure from the customer-specified requirements.

Product disposition for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable. Records of nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

In addition to any contract or regulatory authority reporting requirements, Leach International’s system provides the timely reporting of delivered nonconforming product that may affect reliability or safety. Notification includes a clear description of the nonconformities, which includes as necessary parts affected, customer and/or Leach part numbers, quantity, and date(s) delivered.

Responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions is defined in the procedure.

### 8.4 ANALYSIS OF DATA

LINA determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the Quality Management System and to evaluate where continual improvement of the effectiveness of the Quality Management System can be made. This includes data generated as a result of monitoring



and measurement and from other relevant sources. The analysis of data provides information relating to customer satisfaction (see 8.2.1), conformity to product requirements (see 8.2.4), characteristics and trends of processes and products including opportunities for preventive action (see 8.2.3 and 8.2.4), and suppliers (see 7.4).

## 8.5 IMPROVEMENT

### 8.5.1 Continual Improvement

Leach International continually improves the effectiveness of the quality management system through the use of quality policy, quality objectives, audit results, analysis of data (internal failure and in-service failure), corrective and preventive actions and management review.

Leach also monitors the implementation of improvement activities and evaluates the effectiveness of the results through project meeting, monthly operation scorecard review, quarterly management review supplement and any other scheduled events.

### 8.5.2 Corrective Action

Leach International takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered. The documented procedure defines requirements for:

- a) Reviewing nonconformities (including customer complaints),
- b) Determining the cause of nonconformities
- c) Evaluating the need for action to ensure that nonconformities do not recur,
- d) Determining and implementing action needed,
- e) Records of the results of action taken (see 4.2.4),
- f) Reviewing the effectiveness of the corrective action taken,
- g) Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the nonconformity, and
- h) Specific actions where timely and/or effective corrective actions are not achieved.
- i) Determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.

### 8.5.3 Preventive Action

Leach International determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. The documented procedure defines requirements for:

- a) Determining potential nonconformities and their causes,
- b) Evaluating the need for action to prevent occurrence of nonconformities,
- c) Determining and implementing action needed,
- d) Records of results of action taken (see 4.2.4), and
- e) Reviewing the effectiveness of the preventive action taken.