

Quality Management System

QUALITY MANUAL

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TeraSys Technologies Quality Policy

It is the policy of TeraSys Technologies to engineer and manufacture innovative products to enhance wireless communications that meet the highest quality requirements, following the company and personal principle of “Continuous Improvement.” TeraSys Technologies strives to continuously improve products, processes, and the quality management system by establishing, monitoring, reviewing and acting upon quality objectives.

1.0 Scope and Exclusions

1.1. General

This document is the primary document of the TeraSys Technologies’ Quality Management System (QMS).

The policies contained within this manual are written to conform to ISO 9001:2008. This manual is intended as a working document that describes, as a minimum, the quality management systems to be deployed at TeraSys Technologies.

1.2. Scope

The scope of the Quality Management System (QMS) comprises TeraSys activities and operations associated with TeraSys Corporate offices and the supporting and administrative functions related to these activities and operations.

1.3. Exclusions

This quality manual addresses all requirements of ISO 9001:2008 with the exception of:

1. Clause 7.5.2, “Validation of processes for production and service provision”. Clause 4.2.2.a of ISO 9001:2008 permits the exclusion of certain requirements under specific criteria. TeraSys excludes clause 7.5.2 because TeraSys services do not have to be validated.

2.0 Normative References

- 2.1. ISO 9001 Quality Management Systems – Requirements, 4th edition.
- 2.2. T-AC-001 TeraSys Technologies Accounting Policies & Procedures v.15
- 2.3. Federal Acquisition Regulations (FAR)

3.0 Terms & Definitions

3.1. Terms

3.2. Definitions

3.2.1. Top Management

Top Management is comprised of the managers of marketing, manufacturing & production, engineering, facilities, quality and the president. They are the key personnel and are independent of each other.

3.2.2. SPC

Statistical Process Control is a method of monitoring, controlling, and ideally, improving a process through statistical analysis.

4.0 Quality Management System

4.1. General Requirements

TeraSys Technologies has established and maintains a documented Quality Management System (QMS). TeraSys Technologies continuously monitors and improves the effectiveness of the system in accordance to the ISO 9001:2008 standard.

4.1.1. TeraSys Technologies shall:

- Identify all processes needed for the QMS and their application throughout the standard.
- Determine the interaction and sequence of these processes
- Determine the criteria and methods needed to ensure that both the operation and control of these processes are effective
- Ensure the availability of resources and information necessary to support the operation and monitoring of these processes
- Monitor, measure and analysis these processes and
- Implement actions necessary to achieve planned results and continual improvement of these processes.

4.1.2. TeraSys Technologies shall manage the processes in accordance with the ISO 9001:2008 standard.

4.1.3. If TeraSys Technologies decides to outsource any process that affects product conformance with requirements, TeraSys Technologies shall ensure control over such processes. These processes will be identified within the QMS.

4.2. Documentation Requirements

4.2.1. The QMS documentation includes

- Documented statements of the Quality Policy and Quality Objectives
- This Quality Manual
- Documented procedures required by ISO 9001:2008.

- Documents needed by TeraSys to ensure the effective planning, operation and control of its processes.
- Records required by ISO 9001:2008.

4.2.2. Quality Manual

TeraSys established and maintains this Quality Manual which includes

- The scope of the QMS and justification of any exclusions (see 1.3).
- The documented procedures established for the QMS and or reference to them (see 4.2.1) A description of the interaction between the processes of the QMS which is included in the back of this Manual.

4.3. Control of Documents

TeraSys Technologies ensures that all documents required by the QMS are controlled. QMS Documents are controlled in accordance with QP-42-01 Control of Documents & Records.

4.4. Control of Records

TeraSys Technologies establishes and maintains records to provide evidence of conformity to requirements and of the effective operation of the quality management system.

Procedures described in QP-42-01 Control of Documents & Records define the controls needed for identification, storage, protection, retrieval, retention time and disposition of the records.

5.0 Management Responsibility

5.1. Management Commitment

TeraSys Technologies' top management is committed to developing and maintaining an efficient and effective QMS.

TeraSys top management:

- communicates the importance of meeting customer, statutory, and regulatory requirements;
- establishes a quality policy;
- establishes initiatives in the "Strategic Plan";
- conducts management reviews; and
- ensures the availability of resources.

5.2. Customer Focus:

Customers determine the expectations, standards and requirements. TeraSys Technologies strives to understand, meet and exceed these requirements.

Relevant customer definitions include:

- External Customers are product end users.

- Internal Customers are people in the organization.
- The public that can be affected by the product.

Expectations include:

- Product Safety
- Product Liability
- Availability
- Delivery
- Packaging and Shipping
- Conformity

Standards include:

- Customer established written requirements
- Government specifications
- Regulatory specifications

Requirements include:

- Key product characteristics
- Internal product and process specifications
- Internal process procedures
- Purchase material specifications
- Key supplier selection

5.3. Quality Policy

TeraSys Technologies' Top Management has established a Quality Policy, stated at the beginning of this document. This policy is communicated and taught to all employees. Continuous improvement is at the core of the TeraSys Technologies Quality Policy.

5.4. Quality Objectives

Top Management ensures quality objectives are established. Initiatives are measurable and consistent with the quality policy.

- Objectives will be defined and documented.
- Objectives will be periodically reviewed on a schedule basis.
- Objectives will be measurable.
- Objectives will be tracked.
- Improvement actions will be implemented based on results of measurements.

Objectives include but are not limited to:

- Financials
- Process performance
- Yields

- Cycle Time
- Customer Satisfaction

5.5. Quality Management System Planning

TeraSys top management ensures that the planning of the QMS is conducted to meet the requirements of the QMS and the quality initiatives outlined section 5.4. Top management also maintains the integrity of the QMS when changes are instituted.

5.6. Responsibility and Authority

TeraSys top management ensures responsibilities and authorities are defined and communicated within TeraSys (see Organizational Chart at the end of this section).

- The Operations Manager or equivalent, who reports directly to the company President, heads the Quality Assurance initiatives and is responsible for ensuring the adequacy of the quality system.
- The Vice Presidents, Managers and/or Directors, of marketing, manufacturing & production, engineering, facilities, quality and the President form the top management staff. They are the key personnel and are independent of each other. They are jointly responsible for achieving product quality, compliance to the quality system and the operating guidelines within this manual.
- Engineering, Manufacturing and Production, and Quality are jointly responsible for:
 - Supporting the Quality Assurance Policy of Continuous Improvement.
 - Creation, implementation and review of quality plans and quality objectives.
 - Initiation of corrective action to prevent product non-conformance.
 - Identification and recording of product quality problems.
 - Initiation, recommendation and development of preventive measures and solutions.
 - Verification of such preventive measures and solutions.
 - Control of further processing and delivery of non-conforming product until appropriate corrective action of the deficiency.
- Operators who are in charge of inspection and testing of products are responsible for:
 - Identifying and segregating non-conforming products,
 - Monitoring the production process on a scheduled basis, and
 - Maintaining statistical process charts (SPC) and following reaction plans for all significant process characteristics and parameters (where appropriate).

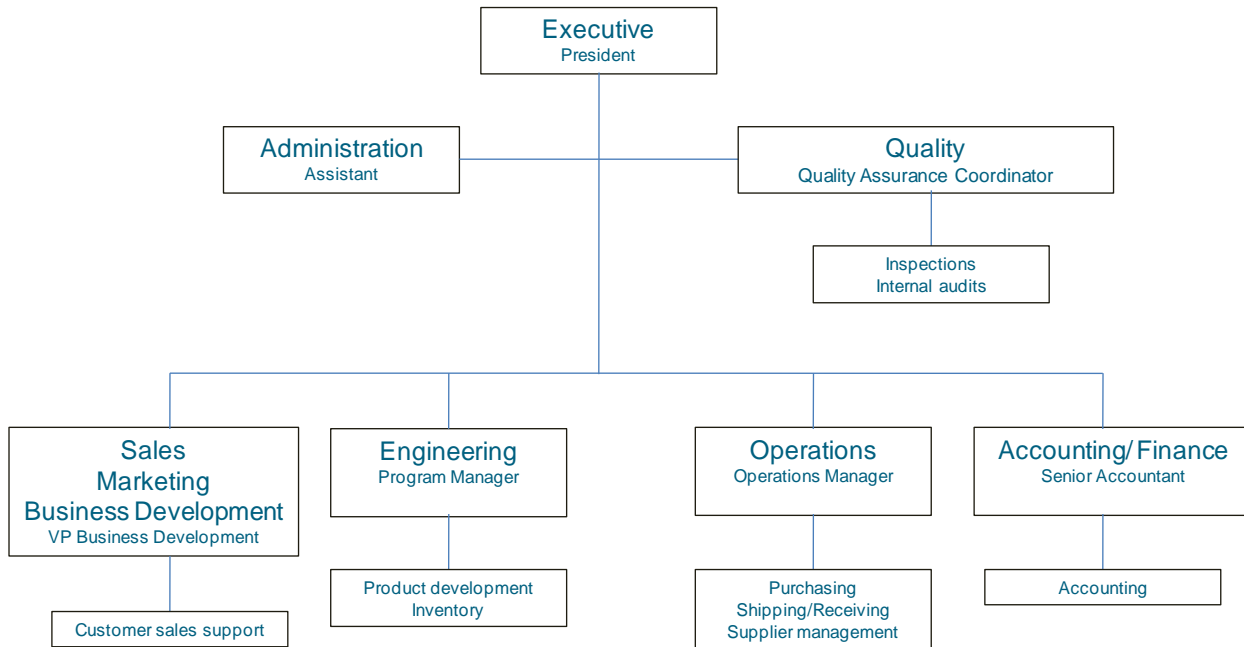


Figure 1-Organizational Chart

5.7. Management Representative

- The manager of quality assurance is designated by the company as the management representative for the quality system and is hereafter referred to as either the Operations Representative (OPS) or Quality Assurance.
- OPS is responsible for ensuring that the necessary processes needed for the quality management system are established, implemented, and maintained.
- OPS has the necessary authority and responsibility to ensure that the operation of the quality system is in compliance with ISO 9001 requirements.
- OPS is responsible for reporting to top management on the performance of the quality management system and any necessary improvements.
- OPS is responsible for ensuring the promotion of awareness of customer requirements throughout TeraSys Technologies.

5.8. Internal Communication

Top management ensures that the effectiveness of the QMS is communicated throughout TeraSys. Information is communicated in various ways including manuals, procedures, work instructions, correspondences, email, website, management reviews, staff meetings, etc.

5.9. Management Review - General

Top Management reviews the QMS at least one time each year to ensure its suitability, adequacy and effectiveness.

- The review will include review of the quality objectives, quality policy, and necessary changes and improvement to the quality management system.
- The review scope goes beyond the verification of the QMS to include processes that extend into the whole organization.
- Records from the review will be maintained in accordance with QP-42-01 Control of Documents & Records.

5.10. Management Review Input

The input to the quality management review shall include:

- Results of Audits
- Customer feedback
- Process performance and product conformity
- Status of preventive and corrective actions
- Review of Quality objectives
- Process Map Review
- Follow-up actions from previous quality management reviews
- Changes that could affect the quality management system
- Recommendations for improvement

5.11. Management Review Output

The output from the quality management review shall include any decisions and actions related to:

- Improvement to the quality management system and its processes
- Improvement of product related to customer requirements
- Resource needs

6.0 Resource Management

Hereafter, TeraSys Technologies may be referred to as “TS.”

6.1. Provision of Resources

6.1.1. Top management shall determine and provide the resources necessary to implement, maintain and improve the QMS.

6.1.2. Top management shall determine and provide resources needed to enhance customer satisfaction by meeting customer requirements.

6.2. Human Resources

6.2.1. TS shall select personnel based on appropriate education, training, skills, certifications and experience to perform work that affects product quality.

6.2.2. TS shall determine the required competence for personnel performing work affecting product quality.

6.2.3. TS shall provide training or take other action to satisfy these needs. The objective is to provide people with skills, knowledge and experience that will improve their competence.

6.2.4. TS shall evaluate the effectiveness of the actions\training taken during management review meetings.

6.2.5. TS shall ensure its personnel are aware of the relevance and importance of their activities and how they contribute to the quality objectives.

6.2.6. Records of continuing education, training, skills and experience will be maintained in accordance with QP-42-01 Control of Documents & Records.

6.3. Infrastructure

6.3.1. TS determines, analyzes, provides and maintains the infrastructure to maintain and continuously improve this quality system and ensure that customer requirements are met.

6.4. Work Environment

6.4.1. TS top management is responsible for ensuring a suitable working environment for TeraSys personnel.

7.0 Product Realization

7.1. Planning of Product Realization

7.1.1. TS plans and develops processes for creating and maintaining products as described in document QP-75-01 Engineering Workflow and/or the project work plan. These documents also define requirements for records necessary to demonstrate process conformity which are maintained in accordance with QP-42-01 Control of Documents & Records.

7.2. Determination and Review of Customer Requirements

7.2.1. TS ensures that all requirements of the product are determined through the contract review system document QP-72-01 Contract Review.

7.2.2. TS reviews all orders through the contract review system prior to accepting the order as described in document QP-72-01 Contract Review.

Records are kept in accordance with QP-42-01 Control of Documents & Records and can include:

- Contract review forms
- Price lists
- Delivery schedules
- Traveler special instructions
- Special packaging instructions

7.2.3. Review of requirements related to the product

TS ensures that product requirements are met through periodic design reviews as described and maintained in the project work plan.

7.2.4. Customer communication

TS communication plan and design review verification and validation schedule is described in the project work plan. Roles and responsibilities are defined during the project kickoff meeting and recorded in the Project Meeting Minutes. TS addresses customer complaints in accordance with QP-84-01 Corrective & Preventive Action.

7.3. Design and Development

7.3.1. TS follows its internal engineering workflow for the design and development of its products which is described in document QP-75-01 Engineering Workflow.

7.3.2. Design & Development Inputs

Design inputs will be determined for each product design. Records of these inputs will be maintained in the project work plan and meeting minutes in accordance with QP-42-01 Control of Documents & Records.

7.3.3. TS ensures that the outputs of design and development enables verification against the design inputs and shall be reviewed and approved prior to release. Records of these outputs will be maintained in the project work plan and meeting minutes in accordance with QP-42-01 Control of Documents & Records.

7.3.4. Design and Development Review

Reviews are conducted at each stage of the development cycle. The project plan determines the representatives and sign-offs required during each of the review stages. Records of the review are maintained in accordance with QP-42-01 Control of Documents & Records.

7.3.5. Design and Development Verification

Verification occurs at the prototype stage prior to the launch stage. Verification ensures that the product is capable of meeting the input requirements and usually is completed prior to submitting product to customer validation as described in QP-75-01 Engineering Workflow. Records of verification are maintained in accordance with QP-42-01 Control of Documents & Records.

7.3.6. Design and Development Validation

Validation occurs during the prototype stage, after verification and prior to launch. Customer validation assures the product is capable of meeting the requirements for the

specified application or intended use as described in QP-75-01 Engineering Workflow. Records of validation are maintained in accordance with QP-42-01 Control of Documents & Records.

7.3.7. Control of Design and Development Changes

Design and development changes shall be identified and records maintained in accordance with QP-42-01 Control of Documents & Records. The changes will be reviewed, verified and validated prior to product implementation. The review of the changes shall include evaluation of the effect of the changes on already delivered product as described in QP-75-01 Engineering Workflow.

7.4. Purchasing

7.4.1. Purchasing Process

7.4.1.1 The operations, quality, and engineering departments shall ensure that all supplies and services procured from suppliers conform to specified requirements.

7.4.1.2 Purchasing information and the verification of purchased product processes and procedures can be found in T-AC-001 TeraSys Technologies Accounting Process & Procedures v.15.

7.5. Production and Service Provision

TS plans and carries out production and service under controlled conditions and the process and procedure is described in document QP-75-01 Engineering Workflow.

7.5.1. Validation of processes for production and service provisions

TS will validate any process change where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any process where deficiencies become known only after the product has been delivered.

Validation will demonstrate the ability of these processes to achieved planned results. TS has established validation processes for appropriate applications in QP-75-01 Engineering Workflow.

7.6. Identification and Traceability

All products that have an impact on product quality, including raw material shall be identified with a part number, lot number, and/or move order number. All final products shall be traceable to all raw material sources for the purposes of investigation. This traceability is documented from receiving to final product and defined in appropriate procedures as described in QP-75-01 Engineering Workflow.

7.7. Customer-Provided Product

TS shall exercise care with customer property while it is under TS' control or being used by TS. TS shall identify, verify, protect and safeguard customer property provided for

use or incorporation into the product. If any customer property is lost, damaged or otherwise found unsuitable for use, this shall be reported to the customer and records maintained as described in the project or product work plan.

7.8. Preservation of Product

All products, at whatever stage of production or delivery, shall be handled in a manner such as to prevent damage or deterioration to the product. The proper handling method will be documented in the appropriate procedures as described in the project or product work plan.

7.9. Control of Monitoring and Measuring Equipment

TS shall determine the needs for measuring and monitoring processes and determine what devices will be used for such to provide evidence of product conformity to requirements. TS has established processes to ensure that monitoring and measurement can be done in such a manner that is consistent with the requirements as described in QP-79-01 Equipment Calibration and/or the project QP-75-01 Engineering Workflow.

8.0 Measurement, Analysis, and Improvement

8.1. General

TS uses data to improve its products and processes. In order to continuously improve, TS plans and implements monitoring, measurement, analysis and improvement processes which can be referred to in QP-84-01 and QP-86-01.

8.2. Customer Satisfaction

TS shall monitor information relating to customer perception as to whether the organization has met customer satisfaction. QP-84-01 Corrective & Preventive Action, QP-86-01 Control of Nonconforming Product describe the methods for obtaining and using this information.

8.2.1. Customer complaints are addressed in accordance with QP-84-01 Corrective & Preventive Action.

8.3. Internal Audits

TeraSys conducts internal audits of the QMS system at planned intervals in accordance with QP-83-01 Internal Audits.

8.4. Monitoring and measurement of QMS processes

TS applies suitable methods for monitoring and measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not met, correction and corrective action shall be taken in accordance with QP-84-01 Corrective & Preventive Action, as appropriate, to ensure conformity of the product.

Measurements are used for managing and evaluation of daily operations and processes. Measurements are used for tracking on-going continuous improvement. Examples of measurements of process performance include:

- Statistical Process Controls (SPC)
- Capability
- Yield
- Process input characteristics
- Process output characteristics
- Specific process characteristics

Evidence of process performance will be maintained.

8.5. Monitoring and Measurement of Product

TS monitors and measures the characteristic of the product to verify that product requirements have been met. This will be carried out at appropriate stages of product realization in accordance with QP-75-01 Engineering Workflow. Acceptance criteria records will be maintained. Records of inspection, including signature of authorized personnel, will be maintained in accordance with QP-42-01 Control of Documents & Records. This includes:

- Inspection and test reports
- Product acceptance forms
- Certificates of Compliance

Product release shall not proceed until planned arrangements have been satisfactory completed unless approved by a relevant authority, and where applicable, by the customer.

When selecting methods for ensuring product conformity, TS will consider the following:

- The product characteristics
- Accuracy and repeatability of the measurement means
- Inspector skills needed
- Equipment, tools and software required
- Location of measurement points within the product realization flow
- Customer or Regulatory witness or verification points as necessary.
- Third party inspection as necessary
- Qualification of people, material, products, processes and the QMS.

8.6. Control of Nonconforming Product

TS ensures that product that does not meet requirements is identified and controlled to prevent use or delivery of the product. MRB and QP-86-01 Control of Nonconforming Product define the responsibilities and authorities for the disposition of the non-conforming material.

8.7. Analysis of Data

For the purpose of continuous improvement, TS shall determine, collect and analyze appropriate data to demonstrate the quality system suitability and effectiveness. The data provides information for:

- Customer satisfaction
- Conformity of product requirements
- Process and product characteristics
- Suppliers

8.8. Continual Improvement

Rather than waiting for problems to reveal opportunities for improvement, TS management shall continually seek to improve the effectiveness and efficiency of the processes of the organization. The organization has a process in place to identify and manage improvement activities. This process is partially based off of results from the following:

- Quality Policy
- Quality Objectives
- Audit Results
- Analysis of Data
- Corrective Action
- Preventive Action
- Management Review

8.9. Corrective Action

The TS corrective action system as described in QP-84-01 Corrective & Preventive Action is used to eliminate the cause of internal or external nonconformities in order to prevent reoccurrence. Corrective Action shall be appropriate to the level of the nonconformity.

8.10. Preventive Action

The TS preventive action system, QP-84-01 Corrective & Preventive Action, is used to eliminate or prevent the occurrence of potential non-conformities. Preventive action is essential to supporting the company's philosophy of continuous improvement.