Polyfet Rf Devices

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QUALITY MANUAL

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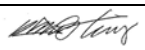
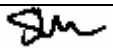
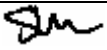
2			7/3/2007	Management Review
1			7/22/04	Page 13
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Rev	Originator	Approved	Date	Pages affected & reason for revision

Areas affected by recent revision are identified by a vertical bar.

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COMPANY PROFILE

Polyfet Rf Devices is a California Corporation formed in 1985. Today the Company employs approximately 25 personnel and operates from a modern, well equipped manufacturing plant based in Camarillo, California.

The Company specializes in the manufacture and supply of MOS Power RF Transistors. The application of products manufactured is vast - from military radios, paging amplifiers, cellular phone base stations to medical uses such as MRI and localized microwave heating treatment. The company led the industry by introducing the world's first gold metalized MOSFET RF Power transistors and the first Mosfet transistor to operate at 1000 Mhz for power RF amplification. The company's products are protected by two patents.

The principal business activities of the Company include the supply MOSFET RF Transistors, Power Amplifier Modules and Hybrid RF Modules. Features are:

- A Line of VDMOS RF Transistors
- A Line of LDMOS RF Transistors
- Transistors operating from DC to 2 Ghz frequency of operation.
- Transistors operating from 6 volts to 50 volts DC supply.
- Custom power amplifier open frame modules.
- Custom hybrid medium power rf amplifiers.
- Services in amplifier design. Software simulation and delivery of finished amplifiers.

A Quality System to ISO 9001, as outlined in this Manual has been developed and implemented to ensure that all customer requirements are satisfied. The Quality System is applicable to all departments and to all activities undertaken by the Company.

QUALITY POLICY STATEMENT

Polyfet RF Devices specializes in the manufacture and supply of quality, reliable Power RF transistors for use in the communication industry.

The objective of the Company is to supply products that are fit for use and have the desired quality in accordance with customer requirements and specifications. Our customers expect reliable, optimum cost products in compliance to specifications delivered on time.

To achieve the above objective and satisfy the customer expectations, the Company is totally committed to implementing and maintaining the Quality Management System based on ISO 9001.

Quality problems arising in various areas are to be identified and solved with speed, technical efficiency and economy. We shall focus our resources, both technical and human, towards the prevention of quality deficiencies to satisfy the organizational goal of "right first time...every time".

The successful operation of the system relies upon the co-operation and involvement of personnel at all levels. Our commitment to quality will ensure the continued success of our Company and the satisfaction of customers and staff.

The Quality Coordinator is authorized to ensure that the requirements of this Quality System are implemented. Any problems that cannot be resolved between departments or personnel shall be brought to my attention for final resolution.

President
Polyfet Rf Devices

QUALITY MANUAL CONTROL

The Quality Coordinator is responsible for the administration, control, review and distribution of the Quality Manual and the Procedures.

Revisions are identified by numbers 0, 1, 2, 3, ... The front page of the manual shows the revision status, approval and reasons for revision. Revisions are issued in the form of loose replacement pages.

Only those changes or revisions approved and issued by the Quality Coordinator in writing shall be official. The text affected by a recent revision is identified by ***italics text***. The front page is re-issued with every change.

Controlled copies are available for the company personnel and to customers if required. The controlled copy number will be identified on the front page, which is pink in color.

The Quality Coordinator shall maintain a distribution list of controlled copies. Controlled copy holders will receive future revisions.

Copies issued to external organizations or personnel are generally uncontrolled. These manuals shall be the current revision. An uncontrolled copy holder will not receive future revisions .

GENERAL

Scope:

This Manual describes the Quality System used by Polyfet RF Devices. The aim is to ensure that:

a. The products supplied by Polyfet RF Devices have the desired quality;

b. The customer and statutory authority requirements are recognized and consistently implemented; and

c. The technical, administrative and human factors affecting quality are under control and oriented towards the reduction, elimination and, most importantly, the prevention of quality deficiencies.

The Quality System is based on the applicable requirements of ISO 9001.

Application:

The Quality System described in this manual is applicable to all work undertaken by Polyfet RF Devices. If an inconsistency exists between this manual and the source control drawing, the latter shall prevail.

Reference Documents:

ISO 9001 Quality Systems - Model for quality assurance in design, development and production.

QPRO-01 Polyfet RF Devices Quality Procedures Manual.
Unless otherwise specified all standards referred to be the latest editions.

Definitions:

Company: Polyfet RF Devices, 1110 Avenida Acaso, Camarillo, CA 93012, USA.

Product: The result of activities or processes. The term "product" is used throughout the Quality System documentation to denote as appropriate, "hardware", software, processed material, and service or a combination thereof.

Quality System: The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

Sub-contractor: Person or company engaged by Polyfet RF Devices to supply or manufacture any of the work included in Polyfet RF Device's scope of work. Sub-contractors include suppliers and vendors.

1. MANAGEMENT RESPONSIBILITY

1.1 Quality Policy:

The President of the Company with executive responsibility for Quality has formally issued the Quality Policy Statement. Detailed and measurable goals are also set and reviewed as part of Management Reviews. The management ensures that this Quality Policy is understood, implemented and maintained at all levels of the company. This is achieved by:

a. The proper induction of all personnel to the Quality System;

b The display of the Quality Policy at prominent locations; and

c. Regular review and audit of quality procedures (to verify their implementation).

1.2 Organization:

1.2.1 Responsibility and Authority:

1.2.1.1 The organization chart (page 10) shows the interrelationship of positions and functions within the company, and the paths of responsibility and authority in relation to quality.

1.2.1.2 The responsibility, authority and interrelationship of every person who manages, performs and verifies work-affecting quality are defined in "Job Descriptions and Specifications". Job Descriptions and Specifications are issued to all personnel and maintained in personnel files. These are available for review at our premises.

1.2.1.3 All personnel may, in their absence, delegate their responsibilities and authority to others as specified in their "Job Descriptions and Specifications". All personnel have the authority to stop work on nonconforming products or services.

1.2.1.4 Procedures together with Job Descriptions and Specifications define the responsibility and authority of personnel for all pertinent quality matters, such as:

a. Initiates action to prevent the occurrence of any nonconformity’s relating to product, process and quality system;

b. Identify and record any product, process and quality system problems;

c. Initiate, recommend or provide solutions through designated channels;

d. Verify the implementation of solutions; and

e. Control further processing, delivery of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

1.2.2 Resources:

1.2.2.1 The company has identified resource requirements for management, performance of work and verification activities. Adequate resources and trained personnel are provided.

1.2.2.2 Company's management believes in "self inspection" and all personnel are trained to carry out the required inspections. Approved sub-contractors and their resources may be utilized for specialized verification activities.

1.2.2.3 Internal Quality Audits are undertaken by representatives (auditors) nominated by the Quality Coordinator or the President. These representatives are independent of the department or function being audited.

1.2.2.4 Adequacy of resources and personnel are formally reviewed every year as part of management review. Resources and personnel requirements are also reviewed as part of contract or order review.

1.2.3 Management Representative:

1.2.3.1 The President, with executive responsibility for quality, has nominated the Quality Coordinator as the company's "Management Representative". The Quality Coordinator is responsible and has the authority to:

a. Ensure that the requirements specified in this Manual and ISO 9001, are implemented and maintained;

b. Report on the performance of the quality system to the Management. As a minimum, one formal annual report identifying the quality improvement opportunities shall be submitted to the management for action during management review; and

c. Co-ordinate with various internal departments or external bodies on matters relating to the company's Quality System.

1.2.3.2 The Quality Coordinator or the nominated representative during his/her absence reports directly to the President.

1.2.3.4 The Quality Coordinator has full organizational freedom to stop, reject and resolve any work or services not conforming to the requirements of the Quality System.

1.3 Management Review:

1.3.1 The Management reviews this Quality System annually as per documented procedure to ensure its continued suitability and effectiveness in satisfying:

a. Stated company policy and objectives;

b. Customer expectations and needs; and

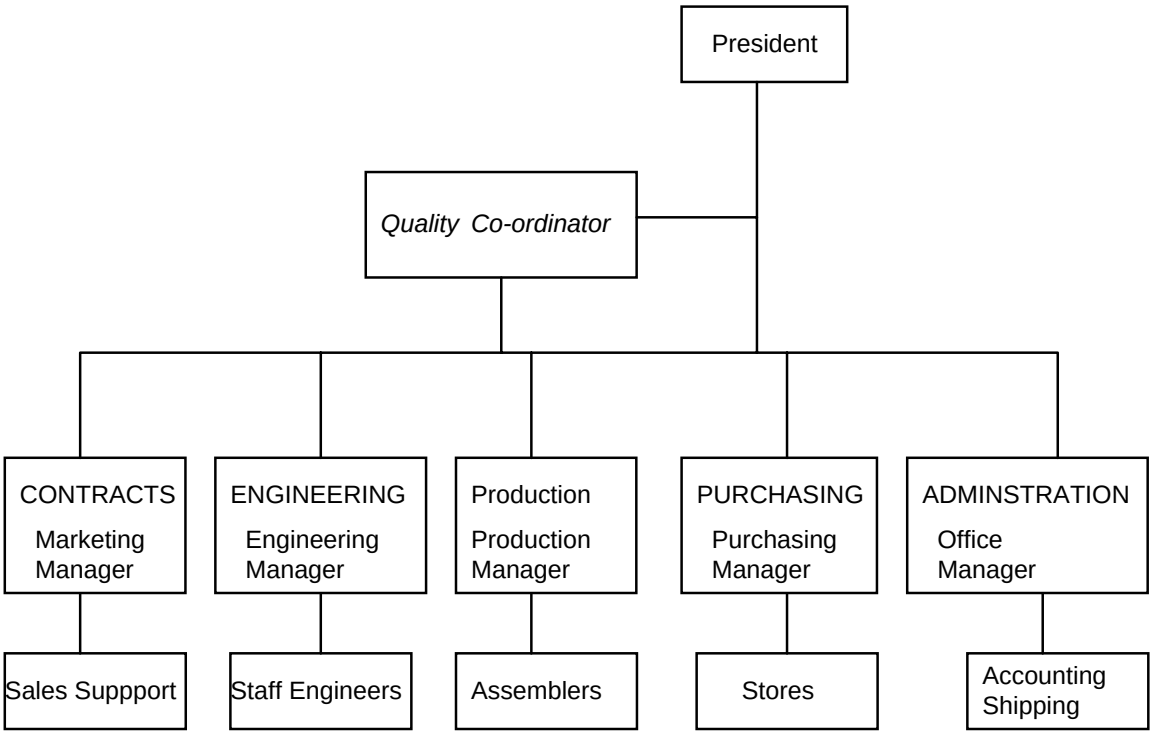
c. Quality standard ISO 9001.

1.3.2 The review is carried out in a meeting chaired by the President and attended by Quality Coordinator, Engineering Manager, Production Manager and Contracts Manager.

1.3.3 During the review, management will effectively utilize all available information, including internal and external quality audit results, customers and third party complaints, quality costs, quality targets (policy and objectives or goals), nonconformance, corrective and preventive actions, in order to improve the system.

1.3.4 Review results are recorded and maintained. The resultant decisions and actions taken will be implemented by the personnel concerned.

For details refer to Management review procedure (Manual QPRO-01 Procedure 4.1).

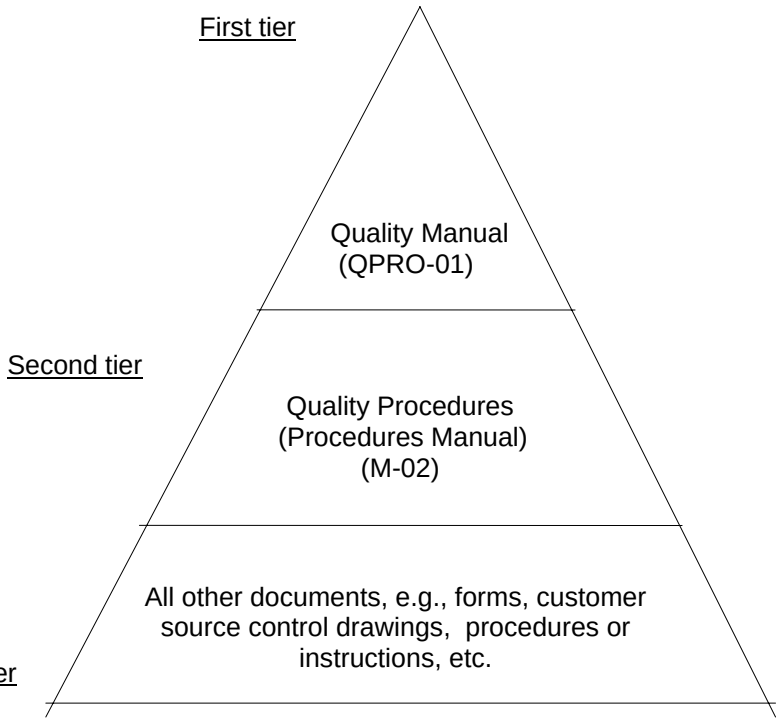


QUALITY ORGANIZATION CHART - POLYFET RF DEVICES

2. QUALITY SYSTEM

2.1 General:

2. 1.1 The Company has developed and implemented a Quality System to ISO 9001 to ensure that products conform to specified or agreed requirements. For practical reasons, this quality management system is produced in a three-tier structure.



2.1.2 Quality Manual (QPRO-01) is the first-tier document. It is a "policy manual" that describes and includes general management policy with regard to quality, organizational structure and responsibilities. It summarizes what is being done, or shall be done, in the various departments and functions of the organization, to achieve the quality objectives.

2.2 Quality Procedures:

2.2.1 Quality Procedures Manual (M-02) is the second-tier document. System Procedures are the tools through which the policies of each activity are implemented. They describe in detail, as applicable, the purpose and scope of the activity; what shall be done and by whom, when, where and how it shall be done; what materials, equipment and documentation shall be used; and how they shall be controlled.

2.2.2 Documents such as Assembly Travelers, Customer Source Control Drawings, Work Instructions, Method Statements, Specific Procedures, Forms, Records, Inspection and Test Specifications (ITSs) and Customer Specific Travelers are classified as third tier documents. They may amplify a quality procedure, detail the manner in which specific tasks are carried out or equipment is operated, used for quality planning, used to record results, etc. All documents that are not included in tier one or tier two are classified as third tier documents.

2.3 Quality planning:

2.3.1 Product quality requirements are defined and documented in second and third tier documents. For major contracts quality planning is done in the form of a Traveler. A Traveler documents those activities, practices and resources necessary to ensure that specified requirements are met. The ITSs, Traveler and Drawing identify the specific inspections and tests that will be carried out on a particular product.

2.3.2 Quality planning is achieved through the ITSs, Traveler and or documented procedures for products, projects or contracts. Consideration shall be given to the following activities during quality planning:

a. Preparation of documents such as ITSs, drawings and procedures;

b. Identification and acquisition of personnel and equipment resources to achieve the required quality;

c. Compatibility of design, production processes and documented procedures;

d. Updating of quality control and inspection techniques and development of new techniques and equipment;

e. Identification and timely development or acquisition of measuring or testing equipment capable of measuring required accuracy;

f. Identification of suitable verification stages in the product realization;

f. Clarification of standards of acceptability for all features and requirements; and

h. Identification and preparation of quality records.

3. CONTRACT REVIEW

3.1 General:

Manual QPRO-01 Procedure 4.3 contains details for review and co-ordination of the proposals (quotations) and contracts (purchase orders).

3.2 Review:

3.2.1 All quotations are reviewed before submission to the customer. All contracts or orders placed on the company by any means (telephone, fax, mail or electronic data transfer) are also reviewed before acceptance. The review is to ensure that:

b. The customer's requirements are adequately defined and documented. For orders received by verbal means, the company ensures that the order requirements are documented and agreed with the customer;

b. To detect and resolve any differences between contract or order requirements to those in the proposal or quotation; and

c. The company has the capability and resources to meet the accepted contract or order requirements.

3.3 Amendment to Contract:

3.3.1 Any variations or amendments to contracts or orders shall be reviewed as per the original. The amendments or variations received from the customer are clearly identified.

3.3.2 Information and details about amendments or variations are promptly communicated to affected departments including sub-contractors.

3.4 Records:

Records of contract reviews are maintained.

3.5 Contract confirmation:

After all contract requirement had been reviewed, a written acceptance notice must be sent to the customer who place the order. The notice should contain as a minimum the following information.

3.6 Contract confirmation:

After all contract requirements had been reviewed, a written acceptance notice must be sent to the customer who placed the order. The confirmation can be in the form of a faxed copy of the customer written purchase order with handwritten or type information with signature. If the confirmation is for a verbal order, it must contain the following information:

a. Customer name
b. Customer’s address, fax and phone number
c. Customer contact person’s name
d. Part number and quantity ordered
e. Customer’s requested ship date
f. Confirmed delivery date
g. Description of any special requirement.
h. Name of person who took the order

4. DESIGN CONTROL

4.1 General:

Manual QPRO-01 Procedure 4.4 contains details for design control and verification of a product in order to ensure that the specified requirements are satisfied.

4.2 Design and development planning:

4.2.1 Design plan(s) shall be developed identifying and describing the design and development activities.

4.2.2 Suitably qualified personnel with adequate resources shall be allocated to each of the design and development activities identified. Design plan is updated as the design evolves.

4.3 Organization and Technical interfaces:

4.3.1 Organization and technical interfaces between different groups that input into design process including customer or regulatory authority are defined in the design plan.

4.3.2 Design procedures ensure that the necessary information is regularly reviewed, documented and transmitted between the groups.

4.4 Design input:

4.4.1 Design input requirements relating to the product are obtained from the performance and functional requirements, historical data, conceptual studies, environmental conditions, contract review records, statutory, customer and the company standards. These are documented or referenced in the design plan or design calculations.

4.4.2 The input requirements are reviewed by the design verifier for adequacy. Incomplete, ambiguous or conflicting requirements are resolved with those responsible for specifying those requirements.

4.5 Design output:

4.5.1 Design plan identifies the required design output requirements for each design activity. The output shall be documented and expressed in terms of requirements that can be verified, e.g., preliminary report, calculations, analysis and drawings. Designer and Verifier shall ensure that design output:

a. Meet the design-input requirements;

b. Contain or reference the acceptance criteria; and

c. Identify those characteristics of the design that are crucial to the safe and proper functioning of the product, e.g., operating, storage, handling, maintenance and disposal.

4.5.2 Design output documents are reviewed before release.

4.6 Design Review:

4.6.1 Design results are reviewed during formal review meetings. Review meetings are conducted at required stages as nominated in the design plan. Representatives of functions concerned with design stage and specialist personnel shall attend these meetings.

4.6.2 Records of reviews in the form of minutes of meeting shall be maintained.

4.7 Design verification:

4.7.1 Design verification activities are planned, documented and assigned to competent personnel. Design verification at nominated stages is undertaken to establish that design output meets design-input requirements.

4.7.2 In addition to conducting design reviews, design verification measures include:

a. Performing alternative calculations;

b. Comparing the new design with similar proven design if one is available;

c. Undertaking tests and demonstrations; and

d. Reviewing the design stage documents before release.

4.7.3 Design verification measures are recorded.

4.8 Design validation:

4.8.1 After successful design verification, design validation where applicable shall be performed to ensure that product conforms to defined user needs and or requirements.

4.8.2 Design validation is normally performed on the final product under defined operating conditions. Different validations shall be undertaken if the product has different intended uses. Records of design validation are maintained.

4.9 Design changes:

All changes and modifications to the design are identified, documented, reviewed and approved by authorized personnel before their implementation.

5. DOCUMENT AND DATA CONTROL

5.1 General:

5.1.1 Manual QPRO-01 Procedure P1.5 contains details for control of all essential documents and data affecting either product quality or the quality system. Documents and data can be generated by the company or issued by the external organizations. Documents and data can be in the form of hard copy media, electronic media or other media.

5.1.2 Documents that are controlled include, Quality Manual, Procedures Manuals, ITSs, Assembly Travelers, Forms, Work Instructions and Specifications.

5.2 Document and data approval and issue:

5.2.1 All documents and data are reviewed and approved for adequacy by authorized personnel prior to issue. Master lists of controlled documents identifying the current revision status are maintained and are readily accessible in order to preclude the use of invalid and or obsolete documents.

5.2.2 The required issues of applicable documents are made available at work locations where operations essential to the effective functioning of the quality system are performed.

5.2.3 Invalid and or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use.

5.2.4 Obsolete documents retained for legal, reference or knowledge preservation purposes are suitably identified.

5.3 Document and data changes:

5.3.1 All changes to the documents and data are reviewed and approved by the same personnel that are responsible for the original issue, unless specifically designated otherwise. The designated functions or organizations (including Customers and Inspecting Authorities) are given access to pertinent background information upon which to base their review and approval.

5.3.2 The nature of the changes is to be identified in the document, appropriate attachments or a separate list.

6. PROCUREMENT

6.1 General:

Manual QPRO-01 Procedure P1.6 contains details for controlling purchasing activities to ensure that the purchased product conforms to the specified requirements.

6.2 Evaluation of sub-contractors (including suppliers and vendors):

6.2.1 The evaluation and selection of sub-contractors is based on their ability to meet sub-contract requirements, including quality requirements (quality system and assurance).

6.2.2 The type and extent of control exercised by the company over sub-contractors is defined and documented in procedures and or purchase orders or sub-contracts. The type and extent of control depend upon the type of product, the impact of sub-contracted product on the quality of final product and sub-contractors' previously demonstrated capability and performance.

6.2.3 A list of acceptable sub-contractors and or records of acceptable sub-contractors is maintained.

6.3 Procurement Data:

6.3.1 Procurement documents shall contain data clearly describing the product ordered, including, where applicable:

a. The type, class, grade or other precise identification;

b. The title or other positive identification and applicable issue of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel; and

c. The title, numbers, and issue of the quality system standard to be applied to the product.

6.3.2 Procurement Orders are reviewed and approved by nominated personnel for adequacy of specified requirements prior to release.

6.4 Verification of Purchased Product:

6.4.1 Company verification of sub-contracted product:

Verification arrangements and method of product release shall be specified in the procuring order when the company elects to verify the procured product at the sub-contractor's premises.

6.4.2 Customer verification of sub-contracted product:

6.4.2.1 Where specified in the contract, the customer or his representative is afforded the right to verify at source or upon receipt that a procured product conforms to specified requirements.

6.4.2.2 The company shall not use the customer verification of the sub-contracted product, either at sub-contractor premises or the company premises, as evidence of effective control of quality by the sub-contractor.

6.4.2.3 Verification by the customer shall not absolve the company's responsibility to provide an acceptable product, nor shall it preclude subsequent rejection by the customer.

7. CONTROL OF CUSTOMER SUPPLIED PRODUCT

7.1 Manual QPRO-01 Procedure P1.7 contains details for verification, storage and maintenance of customer supplied product (i.e., free-issue material) provided for incorporation into the final product or for related activities.

7.2 Customer supplied products are inspected on receipt for identification, certification, quantity, type, and to detect transit damage. No further inspection or tests are performed unless otherwise specified in the contract specifications.

7.3 Customer supplied products from receipt onwards are treated as any other procured products and are controlled according to the requirements of this manual.

7.4 Any product that is damaged, lost, nonconforming or otherwise unsuitable for use, is recorded and reported to the customer.

7.5 Verification by the company does not absolve the customer of the responsibility to provide an acceptable product.

8. PRODUCT IDENTIFICATION AND TRACEABILITY

8.1 General:

Manual QPRO-01 Procedure P1.8 contains details for identification and traceability of the product. Identification and traceability records are maintained.

8.2 Identification:

8.2.1 The company's Product Identification System enables positive identification of each product and its components from applicable drawings or specifications from receipt through all stages for which the company is responsible.

8.2.2 All products are identified by part number and lot code.

8.3 Traceability:

8.3.1 Traceability methods are used for all products.

8.3.2 Each job or production run carries a unique Job Number or Lot Code. If required, individual items have a unique part number or serial number to distinguish apparently identical items.

8.3.3 The Lot Codes are stamped on the materials or recorded by other means ensuring that any item or batch is traceable to the specific point of origin.

8.3.4 Traceability numbers are referenced on all inspection and quality records.

9. PROCESS CONTROL

9.1 Manual QPRO-01 Procedure P1.9 and third tier documents contain details and methods for process control to ensure that all work is performed under controlled conditions.

9.2 All production that directly affects quality are identified and planned to ensure that the processes are carried out under controlled conditions. Controlled conditions include the following:

a. Documented procedures or work instructions defining the manner of production where the absence of such instructions would adversely affect quality;

b. Use of suitable production equipment, suitable working environment;

c. Compliance with reference standards and codes, and or documented procedures;

d. The monitoring and control of suitable processes parameters and product characteristics during production;

e. The approval of processes, personnel and equipment, as required;

f. The criteria for workmanship which shall be stipulated, in the clearest practical manner, e.g., written standards, representative samples or illustrations; and

g. Suitable maintenance of equipment to ensure continuing process capability.

9.3 The requirements for any qualification of process operations including associated equipment and personnel are specified.

9.4 Records are maintained for qualified processes, equipment and personnel.

9.5 Special consideration is given to the manufacture, inspection and testing processes where the results of which cannot be fully verified by subsequent inspection and testing of the product. Such processes require pre-qualification of their process capability and are classified as "Special Processes". All special processes are carried out by qualified personnel using qualified process procedures, documentation and equipment. Special processes are regularly or continuously monitored to ensure that the specified requirements are met.

10. INSPECTION AND TESTING

10.1 General:

10.1.1 Manual QPRO-01 Procedure P1.10 and third tier documents contain details for inspection and testing activities. Inspection and testing is carried out to verify that the product satisfies the specified requirements.

10.1.2 The nature and extent of inspection and testing activities and the records to be established shall be specified in documents such as inspection and test plan, Assembly Traveler, purchase order, drawings and procedures.

10.1.3 Nonconforming products are segregated where practicable and identified by BONDED stickers. The cause of nonconformance is investigated and product disposal and corrective actions are taken as per documented procedures.

10.2 Receiving Inspection and Testing:

10.2.1 All incoming products are inspected or otherwise verified as conforming to the specified requirements before acceptance and release to use or further work. Verification shall be in accordance with the drawings, purchase order or documented procedures. All the required documentation, including objective evidence provided by the supplier, is verified before acceptance.

10.2.2 The nature and amount of receiving inspection and testing depend on the amount of control exercised at the sub-contractor's premises and the recorded evidence of conformance provided.

10.2.3 Incoming goods may be released for urgent production without completion of required inspections or tests or reviews by the personnel nominated in procedures. Products released are identified and or recorded in the ITP or Assembly Traveler or other document in order to permit immediate recall and replacement in the event of nonconformance to specified requirements. Products released under this positive recall system shall be cleared after verification of conformance to the requirements.

10.3 In-process inspection and testing:

10.3.1 In-process inspections and tests as specified in the ITP or Assembly Traveler and or documented procedures are carried out at appropriate points during production to verify conformity of the product.

10.3.2 Product conformance to specified requirements is established by the use of process monitoring and control methods. These activities are signed off on ITP or Traveler and or recorded if required on separate reports.

10.3.3 No product is released for further processing until the required inspections and tests are completed or necessary inspection and test reports are received and verified, except when products are released under positive recall, refer to clause 10.2.3.

10.4 Final Inspection and Testing:

10.4.1 Final inspections and tests as specified in the Traveler or ITS and or documented procedures are carried out to ensure the product meets the specified requirements.

10.4.2 The Quality Plan, ITS or Assembly Traveler and documented procedures will ensure that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements.

10.4.3 No product is dispatched until all the activities specified in the Traveler or ITS and or documented procedures have been satisfactorily completed and the associated data and documentation is available and authorized.

10.5 Inspection and Test Records:

10.5.1 All inspection and test records, which give evidence that the product has been inspected and tested are established and maintained. These records shall show clearly whether the product has passed or failed the inspections and or tests according to defined acceptance criteria.

10.5.2 Records shall identify the inspection authority responsible for the release of the product.

11. CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT

11.1 General:

11.1.1 Manual QPRO-01 Procedure P1.11 and third tier documents contain details and instructions for control, calibration and maintenance of inspection, measuring and test equipment used to demonstrate the conformance of product to the specified requirements. All inspection, measuring and test equipment including test software whether owned by the company or on loan shall be calibrated or verified.

11.1.2 Inspection, measuring and test equipment shall be used in a manner, which ensures that measurement uncertainty is known and is consistent with the required measurement capability.

11.1.3 Test hardware, e.g., Jigs, fixtures, templates, or test software, e.g., computer programs, used for inspection are checked to prove that they are capable of verifying the acceptability of the product prior to initial release and at nominated frequency during use. Records of the checks are maintained as evidence of control.

11.1.4 Where specified in the contract, technical data pertaining to the inspection, measuring and testing equipment is made available if required to customer or customer's representative for verification that the devices are functionally adequate.

11.2 Control procedure:

Procedures and instructions shall ensure the following:

11.2.1 Suitable measuring and test equipment capable of accuracy and precision necessary are selected after identifying the measurements to be made and corresponding accuracy requirements.

11.2.2 All inspection, measuring and testing equipment that can affect product quality are identified and calibrated at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to nationally recognized standards. Where no such standards exist, the basis used for calibration shall be documented.

11.2.3 Methods and processes employed for calibration of inspection, measuring and test equipment are defined, documented and implemented. These shall include details of equipment type, identification number, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory.

11.2.4 Calibrated equipment or the cases containing them are identified with stickers, suitable indicators or approved identification record to show the calibration status where practicable.

11.2.5 Calibration records for inspection, measuring and test equipment are maintained.

11.2.6 When measuring and testing equipment is found to be out of calibration, the validity of previous measurement and test results are assessed and documented.

11.2.7 All inspection, measuring and testing equipment is calibrated and used in an environment, temperature, lighting, vibration, humidity, cleanliness, controlled to the extent necessary to ensure valid measurement.

11.2.8 All inspection, measuring and testing equipment is properly handled, preserved and stored such that accuracy and fitness for use is maintained.

11.2.9 Inspection, measuring and test facilities including test hardware and software are safeguarded from adjustments that would invalidate the calibration settings.

12. INSPECTION AND TEST STATUS

12.1 Manual QPRO-01 Procedure P1.12 contains details for indicating positively the conformance or nonconformance of a product with regard to inspection and tests performed.

12.2 Inspection and test status of the products is identified by using authorized stamps, markings, tags, labels, physical location, records or other suitable means. ITS and or documented procedures shall define the requirements for identification of inspection and test status.

12.3 The identification of inspection and test status shall be maintained throughout production of the product to ensure that only product that has passed the required inspection and tests or released under authorized concession is dispatched.

12.4 “BONDED” tags and stickers are used to identify and segregate the nonconforming product from inadvertent use or delivery. “BONDED” tags or stickers are used during all stages that are incoming, in-process and final inspections.

12.5 “ACCEPTED” tags and stickers or marks are used to indicate satisfactory completion final inspection. Acceptability of the in-process inspections is indicated on the ITS, inspection reports or Travelers or physical location.

12.6 The person or authority responsible for inspection, testing and release of conforming products is identifiable from the records generated or from the signature or numbers on the tags or stickers. The authority for application and removal of status indicators is documented in the procedure.

13. CONTROL OF NONCONFORMING PRODUCT

13.1 General:

13.1.1 Manual QPRO-01 Procedure P1.13 contains details for ensuring the product that does not conform to specified requirements is prevented from inadvertent use, installation or delivery to customers. Controls for identifying, documenting, segregating, reviewing, notification and disposing of nonconforming product are established, documented and maintained.

13.1.2 Nonconformance observed in sub-contractor product shall be notified to the sub-contractor and the disposition and corrective action shall be mutually agreed.

13.2 Nonconforming product review and disposition:

13.2.1 The responsibility and authority for the review and disposition of nonconformance is defined and documented in the procedure.

13.2.2 Nonconforming product observed at all stages, e.g., receiving inspection, in-process inspection, final inspection and reviews, is identified, held, recorded, reviewed and disposed of as per documented procedure.

13.3.3 Disposition may be one of the following:

a. Rework to meet the specified requirements;
b. Accept with or without repair by concession;
c. Re-grade for alternative application; and
d. Reject or scrap.

13.3.4 When required by the contract, the proposed use or repair of a product that does not conform to specified requirements shall be reported for concession to the customer or his representative.

13.3.5 All reworked or repaired items are re-inspected as per the ITS and or documented procedures or to the requirements developed as part of the nonconforming product disposition. The description of nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition.

13.3.6 Records of occurrence of nonconformance, the nature and extent, the disposition, subsequent re-inspection or test results are maintained.

14. CORRECTIVE AND PREVENTIVE ACTION

14.1 General:

14.1.1 Manual QPRO-01 Procedure P1.14 contains details for investigating conditions adverse to quality and implementing corrective and preventive action.

14.1.2 Corrective and preventive action is taken to eliminate the causes of actual or potential non-conformities. The level or degree of corrective and preventive action taken depends on the magnitude of the problem and is commensurate with the risks encountered.

14.1.3 Changes in procedures resulting from corrective and preventive action are implemented and recorded.

14.2 Corrective Action:

The procedures for corrective action shall ensure:

a. Customer complaints and reports of product nonconformity are handled promptly and effectively;

b. Nonconformity relating to product, process and quality system is investigated to determine the cause. Results of the investigation are recorded;

c. Corrective action is determined to eliminate the cause of nonconformity; and

d. Corrective action is taken and it is effective.

14.3 Preventive Action:

The procedure for preventive action shall ensure:

a. All processes and work operations which affect quality, concessions, quality records, nonconformance reports, service reports, audit reports and customer complaints are analyzed to detect and eliminate potential causes of a nonconformity;

b. Steps needed to deal with any problems requiring preventive action are determined;

c. Preventive action is initiated and it is effective; and

d. The relevant information on preventive actions taken including changes to company procedures is submitted for management review.

15. HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY

15.1 General:

Manual QPRO-01, Procedure P1.15 and third tier documents contain details for ensuring that all products from time of receipt to delivery are properly handled, stored, packed, preserved and delivered.

15.2 Handling:

All products are handled properly to prevent damage or deterioration from receipt to delivery. Special handling tools and equipment are inspected regularly to ensure that tools and equipment are adequately maintained and will not damage products.

15.3 Storage:

Secure storage areas are provided to prevent misuse, damage or deterioration of product pending use or delivery. Receipt, and the dispatch to and from such secure areas is controlled. Products in storage are assessed at nominated intervals to detect possible deterioration.

15.4 Packaging:

Packing, packaging and marking processes including materials used are controlled to ensure conformance to the specified requirements.

15.5 Preservation:

Products under company's control are suitably preserved and segregated. Preservation and segregation methods and criteria shall be specified in ITS and or documented procedure.

15.6 Delivery:

Controls are established for the protection of the quality of product after final inspection and test. Where contractually agreed, this protection is extended to include delivery to destination.

16. CONTROL OF QUALITY RECORDS

16.1 All records are properly collected, identified, indexed, filed, accessed, stored, maintained and destroyed as per documented methods (Manual QPRO-01 Procedure P1.16 and third tier documents). Records can be in the form of hard copy media, electronic media or other media. These records include all pertinent subcontractor records.

16.2 Quality records are maintained to demonstrate:

a. The effective operation of the Quality Management System. Such records include Internal audit records, Training records, Calibration records, Sub-contractor approval and surveillance records, Management review records and Corrective action records; and

b. The achievement of the required product quality or conformance to specified requirements. Such records include inspection records, design records, as built drawings, completed checklists or ITS, material certificates, product nonconformance and disposition records.

16.3 All quality records are legible and identifiable to the product involved.

16.4 All records are stored and maintained in such a way that they are readily retrievable in facilities that provide a suitable environment to minimize deterioration or damage and to prevent loss.

16.5 A list of records showing the responsibility, location and retention times is maintained by the Quality Coordinator. The retention time of quality records are established and recorded after consideration to product liability, legal and statutory legislation. Records of product or system conformance can be used to defend the company in the event of product litigation.

16.6 Where agreed contractually, quality records are made available for evaluation by the customer or customer's representative for an agreed period.

17. INTERNAL QUALITY AUDITS

17.1 Manual QPRO-01 Procedure P1.17 contains details for planning and implementing internal quality audits. Internal Quality Audits are carried out to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

17.2 All elements and aspects pertaining to the quality system are audited on a regular basis (at least once a year) as per documented procedures. Audits are scheduled on the basis of the status and importance of the activity.

17.3 Audits are undertaken by competent personnel who are independent of those having direct responsibility for the activity being audited.

17.4 The results of the audits are recorded and brought to the attention of personnel having responsibility in the area concerned and to the President and Quality Coordinator. The management personnel responsible for the area shall take timely corrective action on the deficiencies found by the audit.

17.5 Timely Corrective actions are implemented. Follow-up audits and actions are carried out as per documented procedures. Implementation and effectiveness of the corrective actions are verified and recorded during follow-up.

17.6 Internal audit findings are reviewed by the senior management and where necessary additional steps are taken to improve the quality performance of the organization.

18. TRAINING

18.1 Manual QPRO-01 Procedure P1.18 contains details for induction and personnel training. Training needs of all personnel performing activities affecting quality shall be identified and suitable training provided. The personnel authorized and responsible for identifying the training needs, providing training and maintaining training records is defined in the detailed procedure.

18.2 Annual assessments are carried out to identify the training needs based on the responsibility and authorities allocated for that position.

18.3 All levels of personnel in the company are properly inducted and trained in the tasks they are expected to perform.

18.4 Quality Induction Sessions are conducted for all new employees. Every employee is made aware of the company Quality Policy, Quality System, Job responsibilities and authorities, advantages of proper job performance and effects of poor performance on quality of services, on other employees, customer satisfaction and the economic well-being of the company.

18.5 Personnel performing specifically assigned tasks are qualified on the basis of education, training and or experience.

18.6 Records of training are maintained.

19. SERVICING

When specified in the contract, the company shall establish and maintain procedures for performing, reporting and verifying that servicing meets the specified requirements. Procedures shall include personnel training requirements, equipment requirements, systematic break down of what part to be serviced and how, frequency of service, reporting methods and service status stickers. Manual QPRO-01 Procedure P1.19 contains details that provides guidance for the management to develop servicing plans and methods.

20. STATISTICAL TECHNIQUES

20.1 Identification of need:

Statistical Techniques are used for establishing controlling and verifying process capability and product characteristics. Manual QPRO-01 Procedure P1.20 contains details that provides guidance for management in assessing the need for statistical techniques and identifying and documenting suitable techniques.

20.2 Procedures:

20.2.1 Processes and products requiring statistical techniques shall be identified and detailed third tier documents shall be developed and implemented. Such procedures or instructions shall include:

a. Attribute or variable to be measured;

b. AQLs and control limits;

c. Sampling requirements; and

d. Method of analysis (Pareto Diagram, Histogram, Scatter Diagram).

20.2.2 Where possible sampling plans satisfying the requirements of national or international standards shall be used and referenced in the instructions.

Revision records

Date	Orig.	Description of changes	Approved
7/22/04	KST	Added the following to contract review: **3.6 Contract confirmation:**	

After all contract requirements had been reviewed, a written acceptance notice must be sent to the customer who placed the order. The confirmation can be in the form of a faxed copy of the customer written purchase order with handwritten or type information with signature. If the confirmation is for a verbal order, it must contain the following information:

i. Customer name
j. Customer's address, fax and phone number
k. Customer contact person's name
l. Part number and quantity ordered
m. Customer's requested ship date
n. Confirmed delivery date
o. Description of any special requirement.
p. Name of person who took the order

Date	Orig.	Description of changes	Approved
7/2/07	KST	Management Review	