

QUALITY ASSURANCE MANUAL



QUALITY. PERFORMANCE. RELIABILITY.

QUALITY ASSURANCE MANUAL



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Mission statement from The President

We, at Protek Devices, are committed to be the leading supplier of Transient Voltage Suppression products through continuous quality improvement. Our dedication to quality is embodied in our manufacturing team who strives for constant progress and meeting customer demands in a timely manner.

Rakesh Kansal
President

Protek Devices



PROTEK DEVICES QUALITY POLICY

The objective of Protek Devices is to supply quality products that meet or exceed the requirements of our customers.

The purpose of this Quality Manual is to implement and continuously maintain our commitment to these objectives through a dynamic Quality Assurance System based on the international ISO 9001:2008 standard.

We commit to achieve total customer satisfaction through:

- **Quality**
- **On time delivery**
- **Customer service**

The effectiveness of our quality policy is ensured through:

- review and continuous improvement of the quality management system.
- emphasizing preventive actions.
- effective communication with employees and customers.

Quality control is an integral part of Protek Devices' management and production control. Quality control is not a separate element or function; each and every aspect of the company's day-to-day operations shall be conducted in accordance with the quality policies contained in this manual. The Quality Manual is designed to integrate human, technical and material resources in a manner that results in optimum production consistent with the highest possible quality standards.

There are no exceptions to this commitment. Each and every employee, including management, is expected to understand and work towards our quality commitment. Success requires satisfied customers. This Quality Assurance System reflects Protek Devices total commitment to achieving the goal of meeting the needs of our customers efficiently and safely.

The QA manager is responsible for the implementation and ongoing supervision of the procedures contained in this manual. The administrative responsibility complements but in no way reduces or removes the line responsibility of managers, supervisors or employees of their quality control duties. Quality is everyone's business. There are no exceptions. Any problems that cannot be resolved through normal interdepartmental channels are to be immediately referred to me.

Rakesh Kansal
President



Title: Quality manual

1.0 Purpose / scope

This quality manual defines the procedures used at Protek Devices to ensure that our products and services meet both the customer requirements and quality management system requirements. It also defines the responsibilities and management structure within Protek Devices organization. Top management of Protek Devices agrees and commits to the quality described herein and ensures that it is being followed by all Protek Devices' employees.

2.0 Reference documents

- 2.1 International standard
ISO9001:2008
- 2.2 Protek Devices documents
 - QS-01 Quality Systems Manual
 - QS-4.2.1 Document and Data Control
 - QS-4.2.4 Quality Records
 - QS-5.4 Quality Plans
 - QS-5.6 Management Review
 - QS-6.2.2 Training
 - QS-7.2 Contract Review
 - QS-7.3 Design Control
 - QS-7.4 Purchasing
 - QS-7.5.1 Inspection and Test Status
 - QS-7.5.3 Identification and Traceability
 - QS-7.5.4 Control of Customer Supplied Product
 - QS-7.5.5 Handling, Storage, Packaging, Preservation and Delivery
 - QS-7.6 Control of Inspection, Measurement and Testing Equipment
 - QS-8.1 Inspection and Testing
 - QS-8.2.2 Internal Quality Audits
 - QS-8.2.3 Process Control
 - QS-8.3 Control of Nonconforming Product
 - QS-8.5 Corrective and Preventative Action
 - PM-3540 Preventive Maintenance Procedure
 - QC0096 Subcontractor Control Procedure
 - Any applicable Level 3 procedures



3.0 General

3.1 Company profile

Company name : Protek Devices
Founded : August 17, 1992
Ownership : Protek Devices is a privately owned company
Factory address : 2929 South Fair Lane, Tempe, Arizona, USA
Phone : 602.431.8101
Fax : 602.431.2288
Web : www.protekdevices.com

Business: Protek Devices is a manufacturer of Transient Voltage Suppression (TVS) products designed specifically for the protection of electronic systems from the destructive effects of lightning, Electrostatic Discharge (ESD), Nuclear Electromagnetic Pulse (NEMP) and inductive switching.

3.2 Definitions

The terms and definitions given in ISO9001:2008 apply.

4.0 Quality management system

4.1 General requirements

Protek Devices' quality management system is based on the ISO9001:2008 requirements. In order to establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirement of this standard the model includes:

- a) quality management system model defines sequence and interaction of this application in appendix 1.
- b) organization chart of company administration showing the relationship of various functions within the organization in appendix 2.
- c) determining criteria and methods needed to ensure that both the operation and control of these processes are effective.
- d) determining quality objectives to ensure these processes are effective and the actions needed to implement and achieve planned results and continuous improvement of these processes as necessary.
- e) resources and information to support the operation, monitoring, measurement (where applicable) and analysis of these processes as determined during the management review meeting.



4.2 Documentation requirements

4.2.1 General

The structure of the documentation used in the Protek Devices quality system consists of four levels:

- Level one is this quality manual
- Level two is QS manual
- Level three are internal operating procedures, specifications or working instructions
- Level four are quality records

4.2.2 Quality manual

Protek Devices' quality manual defines the statement of the quality policy, organization, responsibilities and details necessary to meet ISO 9001:2008 quality system requirements. Level 2 and Level 3 procedures and Level 4 Quality records may be used in conjunction with this Quality manual to help satisfy these requirements.

4.2.3 Control of documents

Document control has the responsibility to establish a documented procedure to define the controls needed:

- a) to verify the approval authority of documents for correctness prior to issue.
- b) to review and update, as necessary, and re-approve documents by authorized personnel.
- c) to ensure that change and the current revision status of documents are identified.
- d) to ensure that relevant documents are distributed and remove the obsolete documents at defined locations.
- e) to ensure that documents remain legible and readily identifiable.
- f) to ensure that documents of external origin are identified and their distribution controlled.
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The documents can be in any type of media such as hard copy or electronic media. Document control center shall maintain a master list of the current revision for Protek Devices' controlled documents.

4.2.4 Control of records

Quality records provide evidence of conformity to requirements and of the effective operation of the quality management system. The records can be in any type of media such as hard copy or electronic media. There is a documented procedure for identification, collection, indexing, filing, storage, maintenance, and disposition. The retention period of related records is defined to satisfy statutory, regulatory and customer requirements as a minimum. Quality records must be stored and maintained in a suitable environment and access controlled. The Computer Information System department is responsible to maintain and "back up" electronic data on the computer network system. Records shall remain legible, readily identifiable and retrievable.



5.0 Management responsibility

5.1 Management commitment

Protek Devices' top management is committed to support all efforts to comply with the quality management system for development, implementation and continually improving its effectiveness by:

- a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements.
- b) establishing the quality policy and quality objective.
- c) conducting management reviews.
- d) providing necessary resources to support the quality management system.

5.2 Customer focus

Customer perception is very important and shall be routinely reviewed by management during the management review meeting to ensure that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction.

5.3 Quality policy

We commit to achieve total customer satisfaction through:

- Quality.
- On time delivery.
- Customer service.

The effectiveness of our quality policy is ensured through:

- review and continuous improvement of the quality management system.
- emphasizing preventive actions.
- effective communication with employees and customers.
- reviewed for continuing suitability during annual management review meetings

5.4 Planning

5.4.1 Quality objectives

Management is responsible to define quality objectives and measurements at relevant functions and levels within Protek Devices. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning

The planning of the quality management system includes appropriate controls for materials, machines, equipment, processes, procedures, manpower and other resources.

- a) this quality manual sets the quality procedures to guide all employees to follow and meet the specified requirements.
- b) the quality management system improvements or updates will be discussed during the management review meeting.
- c) the compatibility of the production process, inspection and test procedures are reviewed and approved by the appropriate departments.
- d) the sampling plan and acceptable quality level are developed based on the industry standards and customer requirements.
- f) materials, machines, equipment, human and other resources are carefully reviewed against marketing forecasts.



5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

The responsibility and authority of all the personnel are described in the personnel job description file in the Human Resources department. Every employee has the responsibility to perform the assigned job functions according to the established procedures. The description of departmental functions and responsibilities are defined in appendix 3.

5.5.2 Management representative

The Quality manager shall be the management representative, is appointed by the president of the company and reports directly to the president. The QA manager has the authority and responsibility for:

- ensuring that the quality management system is implemented and maintained according to the ISO 9001:2008 requirements.
- ensuring and promoting awareness of customer requirements throughout the company;
- reporting on the performance of and making recommendations regarding the quality management system to top management for review and action;
- stopping any processes or products from shipping to customers that have potential quality and/or reliability risks;
- acting as liaison with external parties on matters relating to the quality management system.

5.5.2.1 Customer representative

Marketing and/or customer service is responsible for coordinating with customers and concerned departments to address any quality requirements such as quality plans or new product design and development.

5.5.3 Internal communication

Top management shall ensure that the information and action items from the management review meetings are communicated at all levels. It is the responsibility of each supervisor to ensure that his/her subordinates understand the relevance and importance of their activities and how they can contribute to the achievement of the quality objective.

5.6 Management review

General

Protek Devices quality management system shall be reviewed by top management in the management review meeting on a routine basis to determine its continuing suitability, adequacy, effectiveness and opportunity for improvement. The schedule and agenda is prepared by the QA manager and is approved by the president. The management review meeting is chaired by the president and attended by top management. Records shall show topics discussed with objectives and goals. Action items shall also be noted as required. Any additional resources needed shall be identified in order to support the quality management system and its process improvements.



5.6.1 Review input

The input to management review shall include information on:

a) results of audits.

QA manager is responsible for presentation of the previous audit result.

b) customer satisfaction.

Marketing/customer service is responsible for presentation of customer perception survey to determine customer satisfaction level and opportunity for improvement.

c) process performance and product conformity.

The information from customer returns shall be used to analyze actual and potential field failure and their impact on quality.

d) status of corrective and preventive actions.

A review of any corrective actions or preventive actions shall be done.

e) follow up actions from previous management review meetings.

A review of action items from the previous meeting shall be performed.

f) planned changes that could affect the quality management system.

All members will discuss the quality management system element, if any, for changing or improving.

g) recommendation for improvement.

All members could recommend other opportunities for improvement of the existing quality management system.

5.6.2 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

Top management shall ensure adequate resources needed to support all efforts within the quality management system for development, implementation and continually improving its effectiveness.

6.2 Human resources

6.2.1 General

The hiring and induction training is conducted by Human Resources. Basic employee qualification requirements for each position are stated in the job description file located in the Human Resource department. Management through the employee performance review system at least once per year reviews the capability of personnel.



6.2.2 Competence, training and awareness

Necessary competence for personnel performing work affecting conformity to product requirements shall be determined by department managers. Training needs are identified and provided (where applicable) according to documented procedure for all personnel based on the job requirements. Departmental managers shall periodically review hiring or training effectiveness. The results and training records are kept by individual departmental managers / supervisors.

6.3 Infrastructure

The infrastructure shall be maintained as needed to achieve conformity to product requirements including building, work space, associated utilities, process equipment (both hardware and software) and supporting services (such as transport, communication or information services).

6.4 Work environment

The work environment shall be maintained and controlled according to specified requirements including physical, environmental, noise, temperature, relative humidity, safety and housekeeping.

7.0 Product realization

7.1 Planning of product realization

Long term and short term planning of product realization are set according to forecast and market trend. The planning is developed by team approach including:

- product road map
- new business and new package
- manufacturing capacity
- financial performance

7.1.1 Customer requirements

Customer requirements and referenced specifications are reviewed by appropriate departments before implementation.

7.1.2 Acceptance criteria

Acceptance criteria shall be per the established criteria.

7.1.3 Confidentiality

The nondisclosure of proprietary information is required to protect related product information from both parties.

7.1.4 Change control

An engineering change order (ECO) is issued to change processes and is forwarded to applicable departments for approval before implementation to ensure compliance with customer requirements. For proprietary designs, impact on form, fit and function including performance and/or durability may be forwarded to the customer for approval.



7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The requirements related to the product shall be determined before initiating action to ensure that the company is capable of meeting the customer requirements:

- a) customer specified requirements.
- b) control of special characteristics requirements.
- c) statutory and regulatory requirements applicable to the product, and
- d) any additional requirements considered necessary by Protek Devices.

7.2.2 Review of requirements related to the product

Customer purchase orders shall be reviewed by customer service and/or quality/engineering. This review shall be conducted to determine:

- a) if there is any special requirement specified in the order.
- b) if production capacity is available and can meet customer delivery dates.
- c) if there is any deviation from the original contract between both parties.

Any requirement that deviates from the initial review of the contract shall be reviewed and if approved, be coordinated by customer service and/or marketing with the customer. If Protek Devices has agreed to implement the unique requirements it shall be stated in special order specifications on the sales order. Where product requirements are changed, customer service, along with engineering and quality, shall ensure that relevant documents are amended and appropriate departments are made aware of the changed requirements. The final contract must be retained according to quality records retention requirements.

7.2.3 Customer communication

Customer service and/or the marketing department is responsible for coordinating between Protek Devices and the customer to implement effective arrangements for communicating in relation to product information, inquiries, contracts or order handling, amendments, customer feedback, including customer complaints.

7.3 Design and development

The requirements of this element include product development, and manufacturing process design/development.

7.3.1 Design and development planning

The process begins with an evaluation of customer or market needs. When a new product opportunity is identified, the customer or market requirements are determined. A plan is then generated detailing the design and development activities, responsible function for each activity, and timeline for the project. The design team periodically meets to facilitate the sharing and coordination of project activities. A formal review and approval is completed and documented at critical points in the design and development process.



7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained.

The inputs shall include:

- a) function and performance requirements such as customer requirements, specifications, process flow, drawings, special characteristics, materials and packaging.
- b) applicable statutory and regulatory requirements.
- c) information from previous design and developments such as work instructions, acceptance criteria, competitor analysis, other relevant sources.
- d) other requirements essential for development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and development outputs

The design and development output shall be in a suitable form that enables verification against the design and development input and shall be approved prior to release.

The outputs shall include:

- a) meet the input requirements for design and development.
- b) provide appropriate information for purchasing and production. (The service provision does not apply);
- c) contain or reference product acceptance criteria; and,
- d) specify the characteristics of the product that are essential for its safe and proper use.

7.3.4 Design and development review

Reviews of design and development shall be performed in accordance with planned arrangements to evaluate the ability of the results of design and development to fulfill requirements, to identify problems and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage being reviewed. Records of the results of the reviews and any necessary actions shall be maintained. Measurements at specified stages of design and development shall be defined, analyzed and reported with summary results as an input to management review.

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have satisfied requirements. Records of the results of the verification and any necessary actions shall be maintained.



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- 7.3.6 Design and development validation
Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. Wherever practical, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained.
- 7.3.7 Control of design and development changes
Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained.
- 7.4 Purchasing
- 7.4.1 Purchasing process
Protek Devices' purchasing department, along with the engineering and quality departments (when applicable) select suppliers with the capability to meet Protek Devices' needs, to communicate and monitor the appropriate quality requirements to them, and to provide feedback on their performance. Materials that concern product quality are inspected and tested according to the established procedures.
- 7.4.1.1 Approved Supplier List (ASL)
All suppliers (including subcontractors and vendors) of any material, product or service to Protek Devices, that are directly or indirectly part of the Quality Management System, must be approved. The approval of all suppliers is made by the purchasing specialist in conjunction with engineering, quality assurance, and/or any department manager responsible for the use or control of the materials, products or services. Suppliers are selected primarily on their ability to meet or exceed the material, product or service specifications and criteria. The selection may, where appropriate, involve investigating past work for other companies, product testing and/or descriptive information pertaining to the supplier's reputation and claims.
New vendors supplying product to Protek Devices shall be added to the ASL only after completing a Supplier/Subcontractor assessment questionnaire and final approval by the quality assurance department.



7.4.2 Purchasing information

The purchase orders must consist of as a minimum:

- a) The type, brand name, Protek part number and other identifying information.
- b) Specifications and/or drawings.
- c) Technical data.
- d) Terms and conditions.
- e) Onsite inspection access (when required).
- f) Any other delivery and/or acceptance criteria.

7.4.3 Verification of purchased product

Protek Devices shall be given the right to verify material from its suppliers on their premises for product conformity as required. Good quality of materials is essential to the overall product quality manufactured by Protek Devices. Assessment of specified material suppliers may be required and may be evaluated based on one or more of the following:

- a) on-site audit and/or audit questionnaire.
- b) evaluation or statistical data.
- c) inspection and/or test records.
- d) past history.

7.4.3.1 Incoming product quality

All specified materials will be inspected by incoming quality control according to the established procedure, criteria and sampling plan.

7.5 Production and service provision

7.5.1 Control of production and service provision

The manufacturing process is carried out under controlled conditions that include the following:

- a) work is performed according to applicable work instructions / procedures
- b) only equipment and machines, which are within their current calibration, are used in production. The equipment must be maintained in good condition.
- c) product is manufactured in accordance with all necessary drawings and test specifications.
- d) process and equipment must be evaluated and approved by appropriate personnel
- e) accept/reject criteria is stated in Protek Devices' specifications;
- f) process equipment and machines are regularly maintained to ensure continuing process capability and develop a total preventive maintenance system.

7.5.1.1 Work instructions

The process monitoring and operator instruction are documented in the individual work instructions and/or operating procedures. These instructions shall be accessible in the working area.

7.5.1.2 Verification of job set-ups

Whenever processing equipment or machines are changed or reset, the setup is verified to ensure it meets specified requirements.



7.5.1.3 Preventive maintenance

Key process equipment and machines are regularly maintained to ensure a total preventive maintenance system. Preventive maintenance is performed at regular intervals.

7.5.2 Validation of processes for production and service provision

Protek Devices shall validate any processes for production where the resulting output cannot be verified by subsequent monitoring or measurement. and as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results (as applicable) by:

- a) defined criteria for review and approval of the processes.
- b) approval of equipment and qualification of personnel.
- c) use of specific method and procedures.
- d) requirements for records.
- e) revalidation.

7.5.3 Identification and traceability

All products under the control of the Protek Devices' quality system are identified by a QC lot number, QC stamp, lot date code or work order number, part number or other unique description system.

7.5.3.1 Labeling: Where possible, all products are clearly labeled. Product storage facilities, such as bins, shelves, etc., are also marked in such a way that contents are easily and quickly identified.

7.5.3.2 Identification Responsibility: All incoming materials are inspected on receipt to clearly establish its identity, quantity, condition, safe storage requirements and any damage that may have occurred in transit, before labeling with Protek Devices identification. The responsibility for labeling is that of the receiving department. Product that fails inspection is placed in the nonconforming cabinet pending disposition.

7.5.3.3 In-Process Identification: Product that may lose its markings during processing or production handling is relabeled as necessary by any effective means. Maintaining identification is the responsibility of line supervision in each department or function.

7.5.3.4 Plans and drawings: Plans, drawings, and other controlled documents that contain information and details of product use and methods must clearly reference all components, parts and other associated products by the use of the correct identification numbers.



7.5.3.5 Hi-Rel orders: Hi-Rel or military orders shall be traceable to the extent specified in MIL-PRF-19500 for JANTX/JANTXV requirements or as specified in the individual customer drawing. Any traceability requirements over and above that shall be contractually established between Protek Devices and the customer before production begins.

7.5.3.6 Contract Documentation: Where a customer requests special traceability requirements to original materials, outside testing documentation, and/or the point of origin of process materials and product, it is documented as a special contract condition at the time of quotation and/or at the time that the order is placed.

7.5.3.7 Lot Identification: A special lot identification system, that may, if appropriate, overlay or complement the company's standard identification system, is necessary for traceable product. The system must clearly identify the unique product and/or process in a manner that separates it from the other tags or labels.

7.5.3.8 Certification: Any required lot, or certificates that are required to be stamped or recorded on the customer's product must be traceable to their point of origin through Protek Devices' records as required.

7.5.3.9 Inspection Records: All traceability numbers are referenced on all inspection and other quality records.

7.5.3.10 Inspection Points: Under circumstances that require inspection points by qualified personnel, including customer or outside inspector inspection of critical processes, the inspection point is clearly specified on the lot rider. Further processing of materials is held until the specified inspection and approval is complete.

7.5.4 Customer property

The procedures for inspection and release of customer property or consigned materials shall be the same as Protek Devices' standard procedure unless it is specified differently in an established procedure of inspection. In case of materials damaged, lost or unsuitable for use, customer service personnel will inform customer for disposition and maintain a record of this.



7.5.5 Preservation of product

In order to maintain conformity to requirements, preservation of product (as applicable) is based on established specifications to ensure the quality of product including identification, handling, packaging, storage, protection and delivery. Protek Devices recognizes that on-time delivery performance is crucial for customers to meet their production and service requirements. In order to ensure the highest level of on-time performance, production schedules are developed on the basis of established lead-times. Delivery performance is continuously monitored, and corrective actions are implemented when the performance is not satisfactory.

7.5.5.1 Storage and inventory

Materials and finished goods are stored in a controlled environment. First-in first-out (FIFO) and materials shelf life control are used to control issuance of materials. The inventory management system is implemented to optimize inventory to meet customer and production requirements. The inventory shall be audited at specified intervals.

7.6 Control of monitoring and measuring equipment

Inspection, measuring and testing equipment must be routinely calibrated based on established procedures and schedules as well as conform to the specified requirements. Equipment is used in a manner which ensures that measurement uncertainty is known and is consistent with the required measurement capability:

- a) Appropriate inspection, measuring and test equipment are selected based on the type of required measurements and accuracy;
- b) Inspection, measuring and test equipment that can affect product quality must be calibrated or verified, or both, at specified intervals based on international or nationally recognized standards. Calibration service is conducted by qualified personnel, or by a qualified external laboratory.
- c) Procedures for calibration are established and documented which include the following information:
 - equipment type
 - identification number
 - location
 - frequency of checks
 - calibration method
 - acceptance criteria
 - corrective action when results are not satisfactory
- d) Calibration labels are used to identify the calibration status of equipment.
- e) When inspection, measuring and test equipment is found to be out of calibration, the validity of the previous inspection test results must be reviewed and dispositioned.
- f) Environmental conditions for calibrating inspection, measuring and test equipment are documented and strictly followed.
- g) Inspection, measuring and test equipment are handled, preserved and stored so that accuracy and fitness for use are maintained.
- h) Safeguard inspection, measuring and test facilities are established to prevent any unauthorized adjustments, which make the calibration invalid.



- i) Test software or comparative references such as test hardware must be confirmed to prove that they are capable of verifying the acceptability of product prior to release for use during production.

7.6.1 Calibration records

The record retention is defined in a procedure and calibration activities shall include:

- equipment identification, including the measurement standard against which the equipment is calibrated.
- any out of specification reading as received for calibration.
- an assessment of the impact of out-of-specification condition.
- statement of conformance to specification after calibration.
- notification to the customer if suspect material or product may have been shipped.

7.6.1.2 External laboratory

External/commercial/independent laboratory facilities used for inspection, test or calibration service shall be subjected to the same approval criteria as set forth in 7.4.1.1.

8.0 Measurement, analysis and improvement

8.1 General

Protek Devices shall plan and implement the monitoring, measurement, analysis and improvement processes needed:

- a) to demonstrate conformity to product requirements,
- b) to ensure conformity of the quality management system and
- c) to continually improve the effectiveness of the quality management system.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

The customer service department is responsible for conducting a customer satisfaction survey and for collecting this data showing the customer satisfaction level. Results are presented to management at the management review meeting. Performance indicators shall be based on objective data and include, but not be limited to:

- on-time delivery schedule performance
- pricing
- quality
- new products
- customer service



8.2.2 Internal audit

An internal quality audit is performed based on the audit schedule for adequacy and implementation of the quality management system audit. The planned audit schedule must be approved by the quality manager. The result of the audit is brought to the attention of the supervisor or the department head. The department head shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Any open items after the re-audit will be forwarded to the department head for further action. The auditor has the responsibility to follow-up on the audit and to verify record of implementation and effectiveness of the corrective action taken. The audit report must be retained as per record retention procedure. The auditor shall be qualified through an appropriate training program to carry out internal quality audits as necessary. Due to conflict of interest, the auditor shall not audit his or her own work.

8.2.3 Monitoring and measurement of processes

All manufacturing processes are defined with specific details in the documented specifications or work instructions to be used for each process. Each department shall monitor performance to ensure that the consistent quality of the final product is met. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

8.2.4 Monitoring and measurement of product

Product characteristics are inspected and tested based on the established requirements, documented procedures and sampling plans. The area of inspection and testing shall provided appropriate lighting, visual aid, and qualified personnel for evaluation. Finished product is manufactured, inspected and tested against established specifications. Product that fails to meet published specifications shall be rejected by QC and the department supervisor or manager notified of the failure. Product must not be released to the customer until all product has met the specified criteria and the associated data and documentation are available and authorized. Records are established and maintained which give evidence that the product has passed inspection and/or test with defined acceptance criteria.

8.3 Control of non-conforming product

Any product or material, which fails inspection, shall be identified, and controlled to prevent it from subsequent processing or delivery to the customer. It shall be strictly controlled through identification, documentation, evaluation, segregation (when practical), and notification to the concerned functions for further disposition. The responsibility for review and authority for the disposition of non-conforming product shall be defined in accordance with specified documents and procedures. Where applicable, nonconformity review and disposition can be preceded by one of the following:

- a) Material Review Board (MRB) is used for non-conforming incoming material disposition.
- b) Incoming Material Inspection Plan is used for any non-conforming product, material disposition at incoming Q.C.
- c) Final inspection plan is used for all product that fails outgoing QC.
- d) Return Material Authorization is used for any nonconforming product detected after shipping.



- 8.3.1 Control of nonconforming product-supplement
Product with unidentified or suspect status shall be classified as nonconforming product.
- 8.3.2 Control of reworked product
When products are designated for rework/repair, the rework/repair instruction must be documented. In the case where the non-conforming product is reworkable/repairable, once complete, it must be subjected to the same inspection and test procedure as any normal product. Product is put on hold until all required inspections and tests are completed.
- 8.3.3 Customer waiver
For product that fails to meet an individual customer specification, the customer shall be notified in writing of the discrepancy and written customer authorization is required prior to shipment of that product. This applies equally to products or services purchased from suppliers.
- 8.4 Analysis of data
The collection and analysis of data shall be evaluated by the responsible department to demonstrate the suitability and effectiveness of the quality management system. The analysis of data shall provide information relating to:
- a) customer satisfaction.
 - b) conformance to product requirement.
 - c) characteristics and trends of processes and products including opportunities for preventive action, and
 - d) suppliers.
- 8.5 Improvement
- 8.5.1 Continual improvement
Everyone at Protek Devices is encouraged to come forward with ideas for improving any activities that benefits the customer and company. Continuous improvement includes yield, customer complaints, audit results, corrective action and preventive action and management review.
- 8.5.2 Corrective action
Corrective action is important to reduce or eliminate any cause for nonconformities and to prevent their recurrence. The corrective action is used when an internal or external nonconformance occurs such as customer complaint, internal/external audit, and non-conforming product, material or process. The concerned departments take immediate and appropriate actions to contain these nonconformances. Corrective actions include
- a) investigating the causes of non-conformities.
 - b) verifying the root cause of non-conformities.
 - c) initiating and implementing action needed.
 - d) recording the results of action taken.
 - e) reviewing the effectiveness of the corrective action taken.
 - f) if needed, changing procedure or specification.



8.5.2.1 Returned product

When product is returned for nonconformity, a failure analysis shall be performed when required, to identify the potential root cause. If Protek Devices cannot perform such tests, the services shall be contracted from an adequate external laboratory.

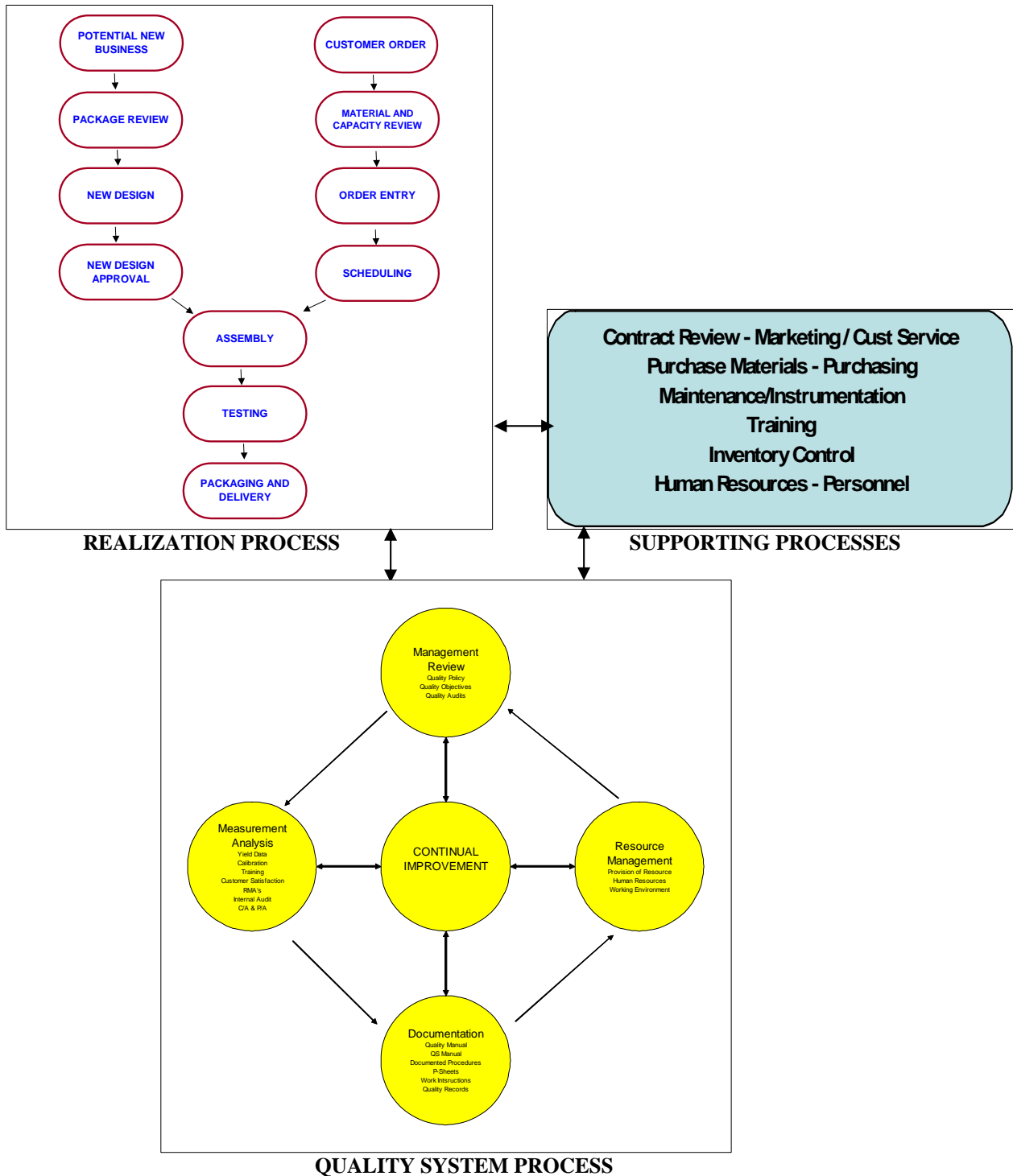
8.5.3 Preventive action

Preventive action is to eliminate the cause of a potential nonconformity or other undesirable situation. A documented procedure shall be established to define 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.
- e) reviewing the effectiveness of the preventive action taken.

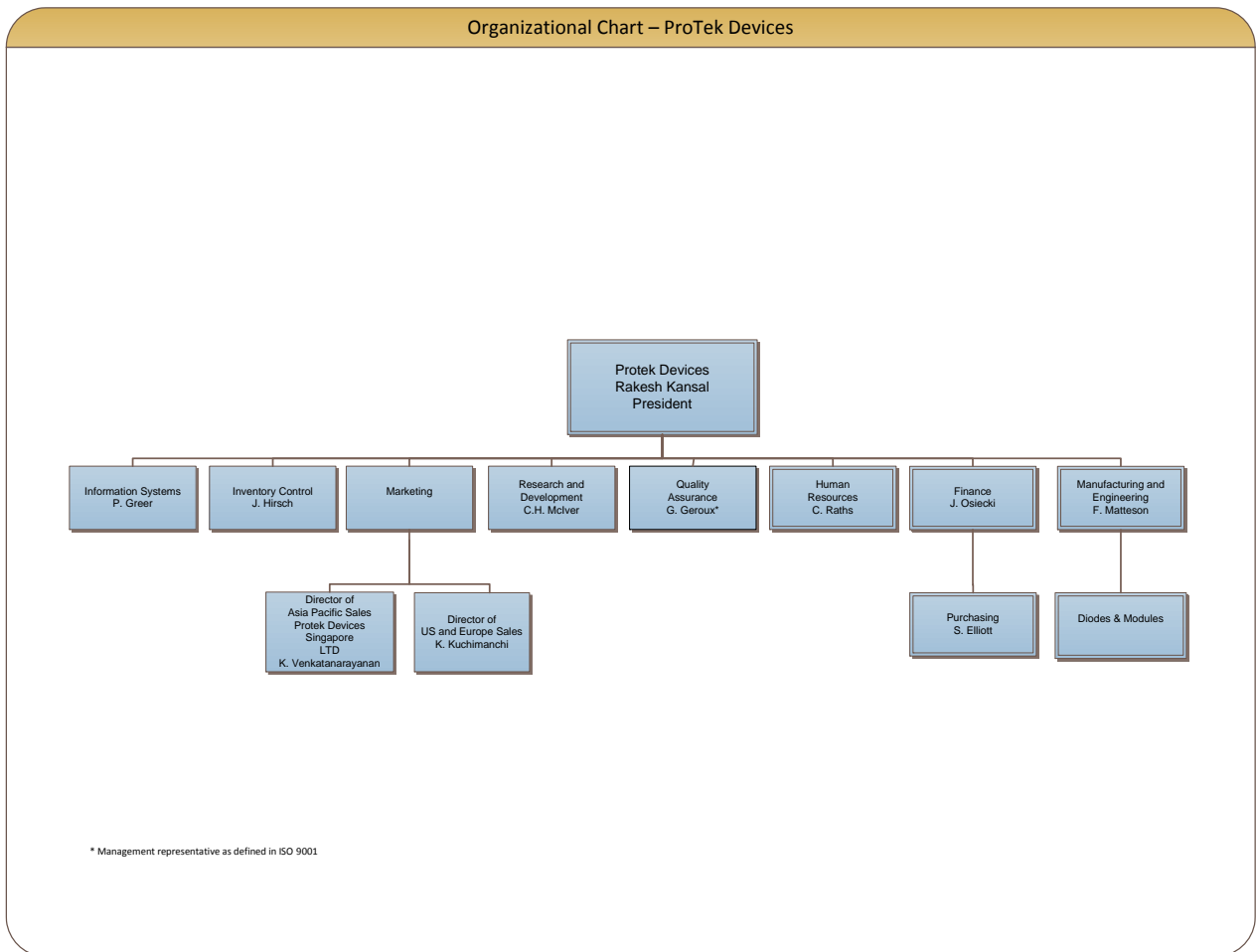


Appendix 1: Sequence and interaction of processes





Appendix 2: Organizational Chart





Appendix 3: Departmental responsibilities

Administration

- Regularly review the company's performance
- Direct involvement in the development of the company's strategy and setting general company direction
- Manage his/her departments of responsibility

New Products

- New products coordination

Material Control Department

- Material control
- Inventory Control
- Receiving

Production Control Department

- Production control

Marketing Department

- Sales and marketing support for customers

Customer Service Department

- Customer service support

Computer Information System Department (CIS)

- Computer System Support
- Telecommunication Support

Human Resources Department

- Recruitment
- Employee relations
- Wage & salary administration
- Benefits, safety and security

Document Control Department

- Control documents
- Control engineering change orders (ECO's)

Purchasing Department

- Vendor approval
- Purchasing negotiation

Instrumentation Department

- Equipment calibration
- Equipment maintenance
- Preventive maintenance



Appendix 3: Departmental responsibilities

Finance Department

- Accounts receivable
- Accounts payable
- Payroll applications
- Cost accounting
- Financial analysis
- Treasury and banking

Quality Assurance and Quality Control

- Incoming quality control
- In-process quality control
- Final acceptance
- Internal quality audit
- Customer audit coordination
- ISO 9001:2008 coordination

Reliability Department

- Reliability & failure analysis
- Special test screening

COMPANY PROFILE

ProTek Devices, based in Tempe, Arizona USA, is a manufacturer of Transient Voltage Suppression (TVS) products designed specifically for the protection of electronic systems from the effects of lightning, Electrostatic Discharge (ESD), Nuclear Electromagnetic Pulse (NEMP), inductive switching and EMI/RFI. With over 25 years of engineering and manufacturing experience, ProTek designs TVS devices that provide application specific protection solutions for all electronic equipment/systems.

ProTek Devices Analog Products Division, also manufactures analog interface, control, RF and power management products. More information regarding analog products can be found at www.protekanalog.com.

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