Quality Manual

ISO9001:2008 / ANSI/ISO/ASQ Q9001-2008

Relia-Tek, LLC
RT-QM-9001
Revision: X1

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GENERAL

0.1 Revision Status

Rev	Description	Approval	Date
X1	Initial Release	H. Jefferson Wood, Pres.	6/26/2015

0.2 Introduction

The Quality Manual presented herein describes the quality management system in operation at Relia-Tek, LLC (hereinafter referred to as Relia-Tek) in Charleston, SC. Relia-Tek has developed and implemented a quality management system to ensure products and services meet customer and applicable commercial, military and regulatory requirements, and to address customer satisfaction through the effective application of the quality management system, including Continual improvement and the prevention of nonconformity.

The manual is divided into four sections modeled on the sectional organization of the ISO 9001:2008 standard. Sections are further subdivided into subsections representing quality system elements or activities. Each subsection starts with a general policy statement expressing the commitment to implement the basic principles of the pertinent quality system element or activity. The general policy statement is followed by more specific procedural policies outlining how the general policy is implemented, and referencing applicable operational procedures and work instructions.

The purpose of this manual is to define and describe the quality system, to define authorities and responsibilities of the management personnel involved in the operation of the system, and to provide general procedures for all activities comprising the quality system. Another purpose of this manual is to present the quality system to our customers and other external interested parties, and to inform them what specific controls are implemented at Relia-Tek to assure the quality of our products and services.

Relia-Tek was formed by H. Jefferson Wood who has over 30 years of experience from NAWC-AD and Raytheon in Indianapolis, IN and SPAWAR-Atlantic in Charleston, SC in designing, testing, fabricating and integrating Command, Control, Computers, Intelligence, Surveillance and Reconnaissance (C4ISR) electrical and mechanical components in United States Navy, Army, Marine Corps and Air Force platforms. Mr. Wood has had roles as the Reliability, Quality, Environmental, Electronics, Mechanical, Industrial, Systems and Project Engineer as well as Project and Program Manager. Mr. Wood values the importance of a Quality Management System and will ensure that all employees of Relia-Tek follow processes and procedures to design quality into all products, verify consistency of product performance and quality and provide reliable design of technical interface products and quality services to all of its customers. Relia-Tek specializes in the design and manufacture of cable and wiring harness and mechanical adapter assemblies required to interface C4ISR systems to military ground, sea and air platforms.

0.3 Compliance and Exclusions [ISO 9001:2008 - 1.2]

This manual and all supporting documents comply with ISO 9001:2008 and ANSI/ISO/ASQ Q9001-2008 Quality Standards with no exclusions. The ISO 9001:2008 referenced sections are included in brackets next to the beginning section titles.

SECTION 4 - QUALITY MANAGEMENT SYSTEM

4.1 General Requirements [ISO 9001:2008 - 4.1]

4.1.1 General Policy

Relia-Tek is committed to establish, document, implement and maintain a quality management system, and continually improve its effectiveness, in conformance with requirements of ISO 9000:2008 International Standard. The scope of the quality management system includes all cable, wiring harness and mechanical assemblies design, manufacturing and services at our Charleston, SC facilities.

4.1.2 Procedural Policies

4.1.2.1 Quality System Processes [ISO 9001:2008 – 4.1a, 4.1b, 4.1c]

a) Processes needed for the quality management system are identified in this quality manual and in associated operational procedures and work instructions. The documentation defines these quality system processes and their sequence and interaction, and instructs on how to implement and apply them throughout the organization.

b) Quality system documentation also defines criteria and methods needed to ensure that the operation and control of quality system processes are effective. This usually includes assignment of responsibilities and allocation of resources for the process, instructions on how to carry out (or operate) the process, and definition of methods for monitoring and/or measuring the effectiveness of the process.

c) Operational Procedure RT04-OP-01, Document Control, explains in more detail how quality system processes are defined and documented.

4.1.2.2 Resources and information [ISO 9001:2008 – 4.1d]

a) The Quality Assurance Manager is responsible for determining resource and information requirements necessary to support the operation and monitoring of quality system processes, and for communicating these requirements to the top management. The top management is responsible for ensuring the availability of necessary resources and information. Section 6.1 of this quality manual, Provision of Resources, explains in more detail how resource requirements are identified and satisfied.

4.1.2.3 Monitoring and measurement [ISO 9001:2008 – 4.1e]

a) The performance of quality system processes is systematically monitored and/or measured. This is to ensure their effectiveness and identify opportunities for improvement.

b) The performance of product realization processes is usually monitored by measuring process parameters and/or product characteristics resulting from the process; and through the program of

inspections and tests applied to the product. The performance of processes required for quality management is usually monitored through internal quality audits. The overall performance of the quality system is monitored by measuring customer satisfaction.

c) Monitoring and measuring activities are defined in Sections 8.1 and 8.2 of this quality manual, and in the corresponding operational procedures.

4.1.2.4 Conformance and Continual improvement [ISO 9001:2008 – 4.1f]

a) Quality management system processes are regularly reviewed by the top management to identify any possible failures or breakdowns, as well as opportunities for improvement. Actions necessary to address actual or potential problems and to improve the quality system are implemented through corrective and preventive actions and management improvement projects. Sections 5.6 and 8.5 of this quality manual and the corresponding operational procedures define how management reviews and corrective/preventive actions are used to ensure conformance and improvement.

4.1.2.5 Outsourced processes [ISO 9001:2008 – 4.1 last paragraph]

a) When processes that affect product conformity are outsourced, special controls are implemented to ensure that these processes meet specified requirements. Such controls may include, as appropriate: evaluation and pre-qualification of suppliers; assessment of supplier realization processes and quality system; monitoring of supplier quality performance; requirements for inspection, testing or other records demonstrating product conformity; or containment and verification of the supplied product. Section 7.4 of this quality manual and the corresponding operational procedures define such purchasing control system.

Associated Documents

- Quality Manual: All sections
- Operational Procedure RT04-OP-01, Document Control

4.2 Documentation and Records [ISO 9001:2008 - 4.2]

4.2.1 General Policy

The scope of quality system documentation is defined. Establishment and revision of documents, and their distribution, are controlled. New documents and revisions are reviewed and approved prior to issue; and are identified with respect to their revision level. Appropriate documents are available at locations where they are used. Obsolete documents are removed from points of use. Documents of external origin are identified and their distribution is controlled.

Quality records are identified and indexed to facilitate their retrieval, and are stored in a suitable environment to minimize deterioration. Quality records are retained for a period of time at least equivalent to the lifetime of the product, or as identified in the Quality Record Master List.

4.2.2 Procedural Policies

4.2.2.1 Scope [ISO 9001:2008 – 4.2.1]

a) Relia-Tek quality system documentation comprises the following types of documents:

- Quality manual (including a documented quality policy) [RT-QM-9001];
- Documented statements of quality objectives
- Operational procedures [RTxx-OP-##];
- Work instructions [RTxx-WI-##-##];
  (Where xx=2 digit number associated to applicable quality manual section)
- Standards and other technical reference materials;
- Engineering documents, including drawings [RTyyxxxz####] (Where yy=2 digit year established, xxx=sequential customer/unique number, z=Letter A-Z), specifications, procedures, and other documents defining products;
- Customer engineering documents;
- Product realization and control plans.

Purpose, scope, and responsibility for controlling various types of documents are defined in Operational Procedure RT04-OP-01, Document Control.

4.2.2.2 Quality Manual [ISO 9001:2008 – 4.2.2]

a) The top level document defining the overall quality management system is the Quality Manual which includes:

- The scope of the quality system, including details of and justification for any exclusions (refer to Section 0.3);
- Description of quality system processes, their sequence, and interrelation; and
- References to documented procedures;

4.2.2.3 Document control [ISO 9001:2008 – 4.2.3]

a) Relia-Tek utilizes electronic documentation wherever practical. Both paper and electronic control systems are defined in Operational Procedure RT04-OP-01, Document Control.

b) New documents and document changes may be initiated by anyone in the organization, but may only be issued by an authorized function. The authorized functions and the rules governing the issue of documents are defined in work instructions RT04-WI-01-01, In-Process Change Orders, RT04-WI-01-02, Issuing Documents, and operation procedure RT04-OP-01, Document Control. All documents are reviewed and approved prior to issue.

c) A paper document is officially issued for use when it is approved by authorized function. An electronic document is issued by being placed in the document directory accessible from the network.

d) Documents are distributed to personnel and locations where they are used. When appropriate and relevant, documents display a distribution list. Electronic documents are available on the

network and are accessible at relevant terminals and computers. Document placement is regulated by Operational Procedure RT04-OP-01, Document Control.

e) Obsolete documents are removed from points of use. Retained masters or copies of obsolete documents are properly marked and are kept separate from active documents. Obsolete electronic documents are removed from the network and, if retained, are stored in directories that are only accessible to authorized personnel.

f) Document changes are reviewed and authorized by the same function that issued the original document. Revised documents are distributed with a change brief summarizing the changes. A master list specifying the latest issues and revisions of its documents is maintained. For electronic documents, only the latest issue and revision of a documents is available on the network.

4.2.2.4 Control of quality records [ISO 9001:2008 – 4.2.4]

a) Quality records are established and maintained to provide evidence that:

- Product designs satisfy design input requirements;
- Materials, components, and production processes meet specified requirements;
- Finished products conform to specifications: and
- The quality system is operated in accordance with documented procedures and that it is effective.

Where required, quality records also include traceability information.

b) Records are established by personnel performing the task, operation, or activity the results of which need to be recorded. Records are dated; and identify the product, person, or event to which they pertain.

c) Records are indexed and grouped to facilitate their retrieval. Cabinets, binders, computer disks, and other storage media containing records are clearly labeled with identification of their content.

d) Records are stored by the same department that established the record. Records are stored in dry and clean areas, and electronic records are regularly backed up. Quality records and documents may not be stored in private desk drawers, unauthorized computer drives, or other obscure locations that are not generally known.

e) Retention periods for quality records are determined on the basis the lifetime of the product or the event to which the record pertains, and on regulatory and contractual requirements.

f) All categories of quality records maintained by Relia-Tek are listed in Operational Procedure RT04-OP-02, Control of Quality Records. The list identifies specific types of records for each category; their storage location; and retention period.

Associated Documents

- Operational Procedure RT04-OP-01: Document Control
- Work Instruction RT04-WI-01-01: In-Process Change
- Work Instruction RT04-WI-01-02: Issuing Documents
- Operational Procedure RT04-OP-02: Control of Quality Records

SECTION 5 - MANAGEMENT RESPONSIBILITY

5.1 Management Commitment [ISO 9001:2008 - 5.1]

5.1.1 General Policy

The top management is ultimately responsible for establishing, implementing, maintaining, and improving the quality system. Management commitment is demonstrated by communicating to the organization the importance of meeting requirements, establishing the quality policy and quality objectives, conducting management reviews of the quality system, and ensuring the availability of necessary resources.

5.1.2 Procedural Policies

5.1.2.1 Top Management [ISO 9001:2008 – 5.1]

a) For the purpose of administrating the quality management system, top management is defined to include the President, and managers responsible for operations, engineering, marketing, sales, human resources, and quality assurance.

5.1.2.2 Customer requirements [ISO 9001:2008 – 5.1a]

a) Top management is committed to communicate the importance of meeting customer as well as regulatory and legal requirements. The management representative is responsible for implementing this commitment by promoting awareness of customer requirements throughout the organization. This responsibility of the management representative is stipulated in Section 5.5, Organization and Communication.

5.1.2.3 Quality policy and quality objectives [ISO 9001:2008 – 5.1b, 5.1c]

a) Top management defines the purpose and objectives for the quality management system. They are documented and communicated in the form of quality policy and quality objectives. Processes for establishing the quality policy and quality objectives are defined in this manual in Section 5.3, Quality Policy, and Section 5.4, Quality System Planning.

5.1.2.4 Management reviews [ISO 9001:2008 – 5.1d]

a) Top management periodically reviews the quality management system to ensure its continuing suitability, adequacy, and effectiveness. The review evaluates current status and performance of the quality system and initiates actions for further improvement of the system. The process for conducting management reviews is defined in Section 5.6 of this manual and in Operational Procedure RT05-OP-01, Management Review.

5.1.2.5 Resources [ISO 9001:2008 – 5.1d]

a) Top management is committed to providing resources necessary for establishing, implementing, and improving the quality management system. Section 6.1 of this manual defines processes for identifying resource requirements and allocation of resources for specific activities and projects.

Associated Documents

- Operational Procedure RT05-OP-01: Management Review

5.2 Customer Focus [ISO 9001:2008 – 5.2]

5.2.1 General Policy

The principal objective of the quality management system is to focus our organization on the customer, and in particular, on customer satisfaction. The key to achieving high customer satisfaction is a good understanding of customer requirements and a capability to consistently fulfill these requirements.

5.2.2 Procedural Policies

5.2.2.1 Determining customer requirements

a) Customer requirements are understood broadly to include all aspects of products and associated services that can influence customer satisfaction. When relevant, this may also include customer needs and expectations.
b) Customer requirements are determined and verified through the process of order review. This process is defined in Operational Procedure RT07-OP-01, Contract Review.

5.2.2.2 Customer needs and expectations

a) When appropriate, customer needs and expectations are determined and are incorporated into product requirements. Marketing is responsible for collecting and analyzing information on customer needs and expectations. The purpose is to gain understanding of:

- Customers use (and misuse) of the product;
- Product interfaces with customer's other products and/or operations;
- Product features and characteristics most important to customers, and which are perceived to be the strengths and weaknesses of the product or service.

b) Information about customer needs and expectations is collected and developed from various sources. These include:

- Trends in stated customer requirements and developments in pertinent legal and regulatory requirements;
- Customer surveys and direct contacts with customers;

- Expressions of customer satisfaction and dissatisfaction, including customer complaints, and other customer feedback;
- Trade magazines, conferences, seminars, etc.; and
- Benchmarking against competitive products.

c) Information about customer needs and expectations is also extracted from customer feedback and complaints, and customer satisfaction data. Operational Procedures RT07-OP-02, Customer Feedback and Complaints, and RT08-OP-01, Customer Satisfaction, define how this data is collected and used.

5.2.2.3 Fulfillment of customer requirements

a) The whole quality system is designed and implemented to ensure that customer requirements can be consistently fulfilled. Quality system processes that most directly contribute to achieving this objective are those related to the control of product realization processes and to monitoring and measuring of product. Sections 7 and 8 of this manual define these processes.

Associated Documents

- Operational Procedure RT07-OP-01: Contract Review
- Operational Procedure RT07-OP-02: Customer Feedback and Complaints
- Operational Procedure RT08-OP-01: Customer Satisfaction

5.3 Quality Policy [ISO 9001:2008 – 5.3]

5.3.1 General Policy

Relia-Tek is committed at all levels to meet customer requirements and increase customer satisfaction through the continual measurement, review and improvement of our products, services, and the effectiveness of the quality management system.

“Customers are most satisfied and will return for future support when Reliable Technology is designed into a Quality Product delivered on time with superior service from inception to delivery and through fielding and sustainment.”

MISSION STATEMENT

Long-term success can only be achieved by fully satisfying and striving to exceed our customers’ expectations regarding the quality of our products and the timeliness and dependability of our delivery and service.

Thus, it our goal to provide our customers with reliable designs, quality products, timely delivery, and dependable service. We strive to produce and supply to our customers the most technologically advanced products available, without defects at competitive prices.

In order to accomplish these goals we will maintain a quality system modeled after the ISO-9001 standard, and will work to continually improve quality in our products and service through effective quality-enhancing techniques to maximize customer satisfaction.

5.3.2 Procedural Policies

5.3.2.1 Authority [ISO 9001:2008 – 5.3]

a) Quality policy is established by the top management and is approved by the President. Any changes to the policy must be approved by the President.

5.3.2.2 Role of the policy [ISO 9001:2008 – 5.3a, 5.3b, 5.3c]

a) The main role of the quality policy is to communicate the company's commitments and goals with regard to quality, and to define principal objectives for the quality management system.

b) The quality policy provides a framework for establishing specific quality objectives, and provides direction for the continual improvement effort. The use of quality policy in setting quality objectives is addressed in this manual in Section 5.4, Quality Planning. The use of the policy to facilitate continual improvement is explained in Operational Procedure RT08-OP-02, Continual Improvement.

5.3.2.3 Communication [ISO 9001:2008 – 5.1d]

a) The quality policy is posted throughout the company, and its role is explained and discussed at the general orientation training provided to all employees.

b) The quality policy is also communicated to customers, consumers and other interested parties. For this purpose, it is displayed in the reception area and posted on the company's internet site.

5.3.2.4 Review [ISO 9001:2008 – 5.1e]

a) The quality policy is periodically reviewed within the framework of management reviews of the quality system. This is to ensure its continual relevance and suitability. The process for reviewing the quality policy is defined in Operational Procedure RT05-OP-01, Management Review.

Associated Documents

- Operational Procedure RT05-OP-01: Management Review
- Operational Procedure RT08-OP-02: Continual Improvement

5.4 Quality System Planning [ISO 9001:2008 – 5.4]

5.4.1 General Policy

Quality objectives are established to support and implement the quality policy and continual improvement. Quality planning includes identification and determination of quality system processes (including any exclusions of ISO 9001 requirements); priorities for Continual improvement; and resources needed to achieve quality objectives and to maintain and improve

the quality system. Quality plans are periodically reviewed and updated to maintain the integrity of the quality system during organizational and other changes.

5.4.2 Procedural Policies

5.4.2.1 Quality objectives [ISO 9001:2008 – 5.4.1]

a) Quality objectives are established throughout the organization to implement the quality policy, to meet requirements for products and processes, and to improve quality system and quality performance.

b) Quality objectives define the direction and priorities for continual improvement. Use of quality objectives for facilitating continual improvement is explained in Operational Procedure RT08-OP-02, Continual Improvement.

c) Quality objectives are classified into the following four categories:

- **Policy objectives**: These are principal, strategic objectives that apply to the whole organization. They are typically included in the quality policy itself, or may be communicated in memoranda from the top management. Policy objectives are authorized by the President.
- **Quality performance objectives**: These objectives set specific, measurable targets for improving operational performance to ensure product conformity and customer satisfaction. They apply to departments and functions having direct responsibility for activities that require improvement. Performance objectives are established, documented, and monitored within the framework of management reviews of the quality system, in accordance with Operational Procedure RT05-OP-01, Management Review.
- **Product quality objectives**: These objectives pertain to improvement of products and associated services. Product objectives are established by the President and top executive managers responsible for marketing and product development. They can be documented in product briefs, memoranda, or minutes of meetings; and apply to functions responsible for research, design, and development of products and services.
- **Quality system objectives**: These objectives pertain to improvement of quality system processes and performance. Quality system objectives are established, documented, and monitored within the framework of management reviews of the quality system, in accordance with Operational Procedure RT05-OP-01, Management Review.

5.4.2.2 Quality system planning [ISO 9001:2008 – 5.4.2]

a) Quality system elements and processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. The purpose of the quality system is:

- To achieve the quality policy;
- To ensure and demonstrate our ability to provide a consistently quality product that meets customer and vehicle platform requirements and standards;
- To ensure high level of customer satisfaction;

- To facilitate Continual improvement; and
- To comply with requirements of the ISO 9001 standard.

b) The output of quality system planning is documented in this quality manual, in associated operational procedures, and in other referenced documents. These documents identify and define all elements and processes of the quality system.

5.4.2.3 Product realization and verification planning [ISO 9001:2008 – 5.4.2]

a) Planning of product realization, verification, and validation processes is addressed in Section 7.1 of this manual.

5.4.2.4 Continual improvement planning [ISO 9001:2008 – 5.4.2]

a) Improvements of the quality system are planned within the framework of management reviews. The output of this planning is expressed in the form of quality system objectives, as defined above in 5.4.2.1 c) of this section, and in Operational Procedures RT08-OP-02, Continual Improvement; and RT05-OP-01, Management Review.

Associated Documents

- Operational Procedure RT05-OP-01: Management Review
- Operational Procedure RT08-OP-02: Continual Improvement

5.5 Responsibility, Authority and Communication [ISO 9001:2008 – 5.5]

5.5.1 General Policy

Functions and their interrelation within the company are defined and communicated. Top management appoints a management representative responsible for establishment and maintenance of the quality system, and for reporting to the top management on the performance of the system. Issues regarding the quality system are communicated internally though distribution of pertinent documents, meetings, training and awareness programs, and management reviews.

5.5.2 Procedural Policies

5.5.2.1 Responsibility and authority [ISO 9001:2008 – 5.5.1]

a) Departments, groups and functions within the company, and their interrelations, are defined in the organizational chart enclosed at the end of this section.

b) All departments and functions in the company are responsible for implementing, maintaining, and improving the quality system.
Following specific responsibilities and authorities are assigned:

Top Management

- Formulates the quality policy
- Provides resources necessary to maintain and improve the quality system
- Conducts management reviews of the quality system

Engineering

- Develops design and prototype quality plans
- Prepares (or reviews) design input specifications
- Designs products and product improvements
- Conducts design reviews
- Verifies and tests designs
- Documents design outputs
- Assists in product realization and verification planning

Production Control

- Schedules production
- Established production work orders

Production

- Plans production facilities, equipment, and processes
- Develops production processes
- Develops process operator and set-up instructions
- Controls and monitors processes
- Conducts in-process inspections
- Applies and maintains in-process product identification
- Maintains production equipment
- Provides training for its personnel

Purchasing

- Selects qualified suppliers and subcontractors
- Prepares and approves purchasing documents
- Monitors and evaluates supplier performance

Receiving

- Receives purchased products
- Performs first-stage receiving inspection
- Applies or verifies product identification for purchased products
- Operates the material stockroom

Shipping

- Packages products (secondary packaging)
- Ships products to customers
- Operates the finished product stockroom

Marketing and Sales

- Conducts market research to anticipate customer expectations
- Determines customer satisfaction
- Establishes specifications for new products (product briefs)
- Advertises and promotes company's products
- Monitors the quality performance of competitors
- Carries out contract and order reviews

Customer Service

- Provides customer liaison and service
- Provides product information
- Handles customer feedback and complaints

Human Resources

- Defines personnel qualification requirements
- Implements measures to motivate personnel
- Conducts company-wide training

Quality Assurance

- Establishes and maintains the quality management system
- Audits implementation and effectiveness of the quality system
- Identifies opportunities for improvement of the quality system
- Develops quality plans and control plans
- Initiates corrective and preventive actions
- Maintains and calibrates measuring and test equipment
- Carries out subcontractor quality surveys and audits
- Performs inspections and testing
- Identifies the need for the use of statistical techniques
- Handles nonconforming products
- Coordinates document control activities
- Maintains, or coordinates the maintenance of quality records
- Coordinates collection of quality performance data
- Provides required training for its personnel.

5.5.2.2 Management representative [ISO 9001:2008 – 5.5.2]

a) The Relia-Tek Quality Assurance Manager reports directly to the President and has the authority and responsibility to:

- Ensure the quality management system is implemented, maintained and continually improved;
- Promote awareness of customer requirements throughout the organization;
- Report to the top management on the performance of the quality system, including needs for improvement; and
- Coordinate communication with external parties on matters relating to the quality system and ISO 9001 registration.

5.5.2.3 Internal communication [ISO 9001:2008 – 5.5.3]

a) Internal communication regarding the quality system flows two ways:

- The management communicates to the organization the quality policy and objectives; customer and regulatory requirements; product and process specifications; verification and validation requirements; and instructions to implement and use the quality system.
- The organization communicates to the management information and data regarding customer needs and expectations, customer satisfaction, quality performance, the effectiveness of the quality system, and opportunities for improvement.

b) The information is communicated through manuals, procedures, instructions, drawings, specifications, quality records, reports; and through training, on-the-job instruction, and meetings. Operational Procedures RT04-OP-01, Document Control and RT06-OP-01, Training and Awareness, regulate these activities.

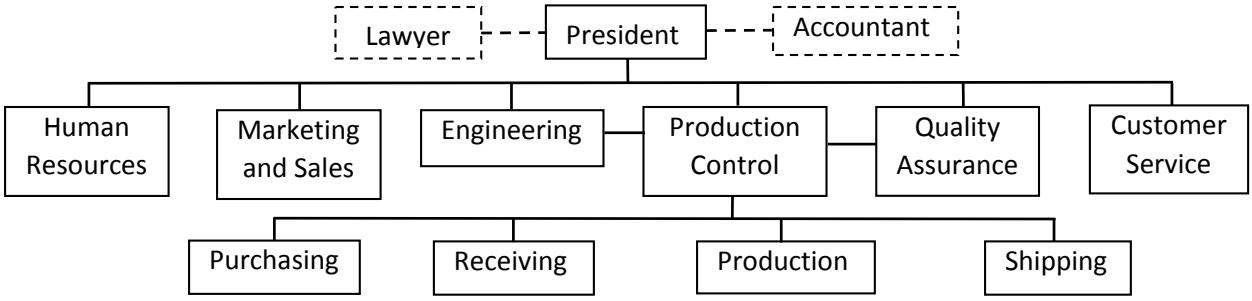
c) Management review meetings ensure proper communication to the organization. The meetings provide the framework to report on status of quality-related issues and activities, and to formulate policies and directives to change and/or improve the quality system. This process is defined in Operational Procedure RT05-OP-01, Management Review.

d) The Quality Assurance Manager has responsibility to ensure all pertinent documents, reports and records are distributed to appropriate personnel, and that information and data about quality performance and the effectiveness of the quality system are reported to top management.

Associated Documents

- Operational Procedure RT04-OP-01: Document Control
- Operational Procedure RT05-OP-01: Management Review
- Operational Procedure RT06-OP-01: Training and Awareness

Relia-Tek Organizational Chart



5.6 Management Review [ISO 9001:2008 – 5.6]

5.6.1 General Policy

Top management conducts periodical reviews of the quality system. The review evaluates the suitability and effectiveness of the system, identifies opportunities for improvement, and considers the need for changes to the quality policy and quality objectives. Results of the review are documented.

5.6.2 Procedural Policies

5.6.2.1 General [ISO 9001:2008 – 5.6.1]

a) The purpose of management reviews is to:

- Evaluate the suitability, adequacy and effectiveness of the quality system;
- Consider changes to the quality management system and to the quality policy and quality objectives; and
- Identify opportunities for improvement of the quality system, processes and products.

b) Management reviews are chaired by the President and are attended by managers representing Quality Assurance, Marketing, Engineering, Production, Purchasing, and Human Resources.

c) Management reviews are conducted at least once a year. More frequent reviews are scheduled in periods when organizational or product changes, or other circumstances require increased attention and input from the top management.

5.6.2.2 Review input [ISO 9001:2008 – 5.6.2]

a) Input into the management reviews consists of information and data related to quality performance of the organization. At a minimum, this includes:

- Results of audits,
- Customer feedback and complaints,
- Process performance and product conformance data,
- Status of preventive and corrective actions,
- Organizational changes,
- Other changes that could affect the quality system,
- Follow-up actions from earlier management reviews, and
- Recommendations for improvement.

Section 8.4 herein, Analysis of Data, and Operational Procedure RT05-OP-01, Management Review, defines scope, and method of presentation, of the input information and data.

5.6.2.3 Review output [ISO 9001:2008 – 5.6.3]

a) Management reviews are concluded with actions related to improvement of the quality management system, and improvement of processes and products to better meet customer requirements. The review also identifies resource needs to implement these actions.

b) Results of management reviews are documented in minutes of the review meeting. The minutes include improvement actions, and assign responsibilities and allocate resources for implementation of these actions.

Associated Documents

- Operational Procedure RT05-OP-01: Management Review

SECTION 6 - RESOURCE MANAGEMENT

6.1 Provision of Resources [ISO 9001:2008 – 6.1]

6.1.1 General Policy

Top management is committed to provide adequate resources for the implementation and improvement of the quality system, and for addressing customer satisfaction.

6.1.2 Procedural Policies

6.1.2.1 General

a) Resources required for implementation and improvement of the quality system, and for addressing customer satisfaction, may include people, suppliers, information, infrastructure, work environment, and financial resources.

6.1.2.2 Determination of resource requirements

a) The Management Representative, Quality Assurance Manager and other management personnel involved in the quality system are responsible for determining resource requirements for the implementation and improvement of the quality system.

b) Sales/Marketing Manager is responsible for determining resource requirements for addressing customer satisfaction. This is based on input from other management personnel responsible for activities relevant to particular aspects of customer satisfaction. Operational Procedure RT08-OP-01, Customer Satisfaction explains how information about customer satisfaction is collected and analyzed.

c) The principal forum for determining and communicating resource requirements are management reviews of the quality system. Operational Procedure RT05-OP-01, Management Review, explains this process.

6.1.2.3 Provision of resources

a) Top management has the responsibility and authority for provision of resources.

b) Allocation of resources for particular activities is integrated with the process of defining and initiating the activity. It may take the form of personnel assignments, allocation of space or equipment, training, procurement decisions, budgets, etc.

c) Allocation of resources may be documented in the quality manual, operational procedures, minutes of meetings, memoranda, or any other form. Approval of resource allocations may also be communicated verbally. However, any verbal resource assignments are followed up by email or other written or electronic documentation.

d) Management review of the quality system is the principal forum for allocation of resources for the operation and improvement of the system. All actions initiated by the review are supported by allocation of specific resources necessary for their implementation. Operational Procedure RT05-OP-01, Management Review, defines this process.

Associated Documents

- Operational Procedure RT05-OP-01: Management Review
- Operational Procedure RT08-OP-01: Customer Satisfaction

6.2 Competence, Awareness and Training [ISO 9001:2008 – 6.2]

6.2.1 General Policy

Relia-Tek identifies personnel training needs, provides required training, and evaluates the effectiveness of the training provided. Personnel assigned to perform specific tasks, operations, and processes are qualified on the basis of appropriate education, experience, or training. Employees are made aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives. Records of personnel qualifications and training are maintained.

6.2.2 Procedural Policies

6.2.2.1 Training and Awareness Programs Identification [ISO 9001:2008 – 6.2.1, 6.2.2]

a) Human Resources and Training is responsible for identifying training needs and awareness programs for company-wide participation, such as: general orientation, rules and regulations, quality system, safety, and other company-wide systems and issues.

b) Departmental managers are responsible for identifying competency requirements and training needs in their departments, and for establishing departmental training programs. Departmental training is primarily focused on increasing the skill level in operating equipment and processes, conducting inspections and testing, and using analytical and statistical techniques.

c) In addition, training needs are often identified in response to corrective or preventive action requests (CARs), as nonconformities may be caused by inadequate training.

6.2.2.2. Awareness and training programs [ISO 9001:2008 – 6.2.1, 6.2.2]

a) Relia-Tek provides, or supports, the following categories of company-wide and departmental training and awareness programs:

- **General orientation and quality system awareness training** — Explains how assembly, test or production product is used and how the quality system works to ensure product quality. Provided to all employees.

- **Safety training** — Instructs in safe working practices, use of personal protective equipment, and first aid. Provided to all employees.
- **Use of company-wide systems** — Explains interdepartmental systems, such as product coding/numbering system, bar-code system, and use of computers. Provided to wide groups of employees.
- **External training** — External seminars, conferences, and courses. Provided to individual employees on as-needed basis.
- **Self-study** — Reading magazines, books, and reports. While all employees are encouraged to broaden their knowledge through reading, in some cases self-studying may be required as formal training.
- **Skill training in engineering, production, and quality control** — departmental training in specific skills. Often provided as on-the-job training.

b) Operational Procedure RT06-OP-01, Training, describes in detail the training and awareness programs provided by Relia-Tek.

6.2.2.3 Effectiveness of training [ISO 9001:2008 – 6.2.2]

a) Effectiveness of training is evaluated using the following approaches:

- Follow-up performance evaluation of trained employees;
- Review of the overall performance in areas relevant to particular training programs;
- Consideration of competency and training when investigating causes of quality system failures and product or process nonconformities; and
- A global review of all training and awareness programs, conducted within the framework of management reviews of the quality system.

Operational Procedures RT06-OP-01, Training, and RT05-06-01, Management Review, provide specific methods for evaluating particular categories of training and awareness programs.

6.2.2.4 Training records [ISO 9001:2008 – 6.2.2]

a) Training records are established for all types of training. Human Resources maintains employee credentials, qualifications, and departmental training records.

Associated Documents

- Operational Procedure RT06-OP-01: Training and Awareness
- Operational Procedure RT05-OP-01: Management Review

6.3 Infrastructure and Work Environment [ISO 9001:2008 – 6.3, 6.4]

6.3.1 General Policy

Suitable infrastructure, facilities and work environment are provided as required to achieve product conformity. This includes planning, provision, and maintenance of employee facilities, workspaces, equipment, software, and associated services.

6.3.2 Procedural Policies

6.3.2.1 Infrastructure and Facilities [ISO 9001:2008 – 6.3]

a) Planning of new, and/or modification of existing infrastructure and facilities is usually conducted in conjunction with product or process changes; capacity and/or work force expansions; and other such events. Facilities may also be expanded or modified to improve productivity and/or quality, or to improve the work environment.

b) Departmental managers are responsible for identifying the need and requirements for new, and/or modification of existing infrastructure and facilities in their departments. Requests for significant changes and/or expansions of facilities are submitted to the Management Team for review and approval.

c) When relevant, Quality Assurance reviews the proposed facilities or changes to ensure that they enhance the achievement of product conformity and quality.

6.3.2.2 Supporting services and maintenance of facilities [ISO 9001:2008 – 6.3]

a) Maintenance of Buildings and facilities is performed by in house trades and managed by the Facilities Administrator. This includes regularly scheduled maintenance of lighting systems, HVAC systems, production and process support systems, landscaping and cleaning. Repairs of buildings, facilities, systems and grounds that are beyond the scope of the in house maintenance staff are contracted as needed. The Facilities Administrator is responsible for coordinating and managing maintenance contracts.

b) Production equipment maintenance is addressed in Section 7.5 herein and Operational Procedures RT07-OP-03, Inspection, Measuring &Test Equipment, RT07-OP-04, Process Control and Work Instructions RT07-WI-04-01, Standard Operating Procedure Maintenance and RT07-WI-04-02, Production Environmental Requirements.

6.3.2.3 Work environment [ISO 9001:2008 – 6.4]

a) Human Resources and departmental managers are responsible for ensuring suitable working environment for personnel. This is to include both human and physical factors.

b) Production and Quality Assurance are responsible for identifying those operations where extreme environmental conditions could impact quality performance of personnel and result in

product nonconformities. Were appropriate, limits of exposure and/or mitigating measures shall be defined and implemented for these operations.

Associated Documents

- Operational Procedure RT07-OP-03: Inspection, Measuring & Test Equipment
- Operational Procedure RT07-OP-04: Process Control
- Work Instruction RT07-WI-04-01: Standard Operating Procedure Maintenance
- Work Instruction RT07-WI-04-02: Production Environmental Requirements

SECTION 7 - PRODUCT REALIZATION

7.1 Planning of Product Realization [ISO 9001:2008 – 7.1]

7.1.1 General Policy

Planning of product realization processes includes determination of quality objectives for products; development of required processes and process documentation; and establishment of product verification and validation programs. The plan also defines requirements for records necessary to demonstrate process and product conformity.

7.1.2 Procedural Policies

7.1.2.1 Product quality objectives [ISO 9001:2008 – 7.1a]

a) Quality objectives for products are defined in drawings and specifications contract documents, internal and external standards, product samples and workmanship standards, and applicable commercial item descriptions, military standards, specifications and regulatory requirements.

b) Quality Assurance is responsible for identifying product quality objectives and requirements. This may be integrated with the process of determining customer and product requirements (refer to Operational Procedure RT07-OP-01, Contract Review and/or with defining design input (refer to Operational Procedure RT07-OP-05, Design Control).

7.1.2.2 Product realization planning [ISO 9001:2008 – 7.1b, 7.1d]

a) Product realization planning includes, as applicable:

- Definition and evaluation of manufacturing operations and processes,
- Development of adequate and capable processes,
- Identification of special processes and consideration of associated risks and consequences,
- Establishment and implementation of appropriate process control measures,
- Development of instructions and training for process operators, and
- Requirements for records necessary to demonstrate process conformity.

b) Product realization plans are established in collaboration between Production, Engineering, and Quality Assurance. The plans are defined in various types of production documents, such as process flowcharts, production work orders, control plans, operator instructions, and process validation reports.

c) Operational procedures related to Section 7.5, Operations, explain how outputs of product realization planning are used.

7.1.2.3 Product verification and validation planning [ISO 9001:2008 – 7.1c, 7.1d]

a) Product verification and validation plans determine the inspection and testing program for a product, and for materials and components incorporated into the product. This includes:

- Identification of inspection and testing points,
- Inspection and testing scope, frequency, and method,
- Acceptance criteria, and
- Requirements for records necessary to demonstrate product conformity.

b) Engineering and Quality Assurance are responsible for the development of product verification plans. The plans are defined in various types of documents, such as product drawings and specifications, production work orders, purchasing documents, inspection and testing procedures, and so forth. Documents defining the processing, inspection and testing program for a specific product are collectively referred to as manufacturing control plans. Operational Procedures, RT07-OP-01, Contract Review; and RT07-OP-05, Design Control are used to help define the manufacturing control plan for a particular product.

c) Operational Procedure RT07-OP-06, Initial Supplier Assessment; Work Instruction RT07-WI-06-01, On-going Supplier Assessment; and Operating Procedures RT07-OP-07, Purchasing; RT07-OP-08, Receiving Inspection; RT07-OP-09, Set-up Inspection; RT07-OP-10, In-process Inspection and RT07-OP-11, Final Inspection explain how outputs of product verification and validation planning are used.

Associated Documents

- Operational Procedure RT07-OP-01: Contract Review
- Operational Procedure RT07-OP-05: Design Control
- Operational Procedure RT07-OP-06: Initial Supplier Assessment
- Work Instruction RT07-WI-06-01: On-going Supplier Assessment
- Operational Procedure RT07-OP-07: Purchasing
- Operational Procedure RT07-OP-08: Receiving Inspection
- Operational Procedure RT07-OP-09: Set-up Inspection
- Operational Procedure RT07-OP-10: In-process Inspection
- Operational Procedure RT07-OP-11: Final Inspection

7.2 Customer-related Processes [ISO 9001:2008 – 7.2]

7.2.1 General Policy

Product requirements are determined to include customer requirements and platform, environmental, legal, regulatory, and other necessary requirements that may not be specified by customers. Orders are reviewed to ensure that product and order requirements are defined and can be met, and to resolve any incomplete or conflicting requirements. Verbal orders are confirmed before acceptance. Order amendments and changes are likewise reviewed and are communicated to all relevant functions. Order reviews are recorded. Arrangements for

communication with customers relating to product information, order handling, and customer feedback and complaints are defined and implemented. Where appropriate, operational procedures and work instructions for these activities are established and implemented.

7.2.2 Procedural Policies

7.2.2.1 Customer and Product Requirements [ISO 9001:2008 – 7.2.1, 7.2.2]

a) Catalog versus custom products

1) In determining and reviewing customer and product requirements, Relia-Tek distinguishes between orders for standard catalog products and custom products.

2) Standard catalog products are products manufactured from Relia-Tek or System Manager standard specifications or drawings and manufactured or sold from stock without any modification or customization.

3) Custom products are products designed and/or modified and manufactured to unique customer requirements.

b) Catalog product requirements

1) For catalog products, requirements for product characteristics, packaging, and support are determined and reviewed in the process of designing or developing the product. Operational Procedure RT07-OP-05, Design Control, defines these activities. Particularly relevant are review of design inputs, and design reviews.

2) Other requirements pertaining to orders for catalog products are reviewed in conjunction with order processing. These may be product availability, material finishes, delivery requirements, special packaging or handling requirements. Operational Procedure RT07-OP-01, Contract Review, provides instruction for conducting this review.

c) Custom product requirements

1) For custom products, product requirements are determined and reviewed by the Sales Manager. This often involves input form Engineering, Production, Purchasing, and Quality Assurance, depending on the nature and complexity of the order, and whether a similar order has been recently processed.

2) Custom product requirements are determined and reviewed with regard to requirements specified by the customer; other relevant product requirements not specified by the customer, and the company's capacity and capability to meet all applicable requirements. Operational Procedure RT07-OP-01, Contract Review, provides instruction for conducting this review.

d) Incomplete or conflicting requirements

1) Any incomplete or conflicting requirements are resolved with the customer before acceptance of the order.

e) Verbal orders

1) Verbal orders are confirmed before acceptance. Confirmation must occur by repeating the order requirements back to the customer by fax or e-mail and receiving written confirmation.

f) Amendments

1) Change orders are received and reviewed by the same functions that are responsible for the review of the initial orders. Change orders are communicated to all functions within the organization that may be affected by the change of customer requirements. Operational Procedure RT07-OP-01, Contract Review provides instructions on how to process change orders.

g) Record

1) Reviews of product requirements are recorded. For catalog products, the review record is established by the customer invoice documenting the catalog part number(s). For custom products, it is a copy of the offer acknowledged by relevant departments. Establishment and maintenance of contract review records are explained in Operational Procedures RT07-OP-01, Contract Review, and RT04-OP-02, Control of Quality Records.

7.2.2.2 Customer Communication [ISO 9001:2008 – 7.2.3]

a) Product Information

1) Marketing department is responsible for developing the content and format for company's brochures, catalogs, internet site, and other forms of promotional and product information material. This is based on technical specifications developed by Engineering.

2) Master copies and/or files of documents containing product information are controlled. They are reviewed and approved before release, and are identified by a unique code-number and a revision level. Superseded and obsolete materials are withdrawn to prevent them from being passed or communicated to customers.

3) Only designated personnel from Marketing, Sales, Customer Service and Engineering are authorized to communicate with customers regarding product information. The Marketing manager is responsible for designating these personnel, and for supporting them with training and current product information.

b) Inquiries and order handling

1) Sales department is responsible for receiving customer inquiries and orders. Orders for standard catalog products are reviewed and processed. Inquiries and orders for custom products

are reviewed by the Sales Manager. Engineering, Production, Purchasing, and Quality Assurance may be called to assist with the review of orders for custom products.

2) Handling of order amendments is controlled to the same extent as the handling of initial orders. Amendments are reviewed to verify that the new or modified requirements can be met, and a confirmation of acceptance is communicated back to the customer.

3) Operational Procedure RT07-OP-01, Contract Review, instructs how to handle inquiries, orders, and amendments for standard catalog products and custom products, respectively.

c) Customer feedback and complaints

1) Sales/Sales Support is responsible for receiving and processing customer feedback and complaints. All received customer communication is recorded either on the individual phone log, order history, or customer contact record.

2) Customer feedback and complaints are classified into categories to allow for better tracking of trends and evaluating improvement in specific aspects. Every complaint is communicated to relevant functions within and outside the organization. Customer Service, the responsible department, and Quality Assurance decide how to respond to the customer and, when appropriate, what corrective or preventive actions should be implemented internally.

3) Operating Procedure RT07-OP-02, Customer Feedback and Complaints, provides detailed instructions how to receive, process, and respond to customer feedback and complaints.

Associated Documents

- Operational Procedure RT04-OP-02: Control of Quality Records
- Operational Procedure RT07-OP-01: Contract Review
- Operational Procedure RT07-OP-02: Customer Feedback and Complaints

7.3 Design and Development [ISO 9001:2008 – 7.3]

7.3.1 General Policy

The design and development process is planned. Design activities are identified, qualified personnel are assigned to specific design responsibilities, and organizational interfaces are defined and controlled. Design input is formally documented and reviewed. The design is verified and, when applicable, is validated with prototype testing or by other means. The design output is documented and checked before it is released for production. Design changes are controlled.

7.3.2 Procedural Policies

7.2.2.1 General

a) Relia-Tek designs its own standard C4ISR system interface products as well as customer-specified products and modifications. Engineering is responsible for design. The quality control system for design is defined in Operating Procedure RT07-OP-05, Design Control and Work Instruction RT07-WI-05-01, Drawing Format and Preparation Guidelines.

7.2.2.2 Design Planning [ISO 9001:2008 – 7.3.1]

a) Design Project Engineer or Product Manager is responsible for the planning of design projects, including the identification of design, review, verification, and validation activities; scheduling the project; assignment of qualified personnel; and control of organizational and technical interfaces.

7.2.2.3 Design inputs [ISO 9001:2008 – 7.3.2]

a) Design inputs may be defined and documented in two ways. Design input for company's standard catalog products comes from Marketing in the form of a product brief. Design input for custom products comes from Sales and is documented in a design order. Design inputs are reviewed and approved before their release to the design team.

7.2.2.4 Design outputs [ISO 9001:2008 – 7.3.3]

a) Design outputs are documented on two levels:

- Primary output consists of documents defining the designed product;
- Secondary output supports the design with calculations, analysis, and material selection.

Design output documents are checked and approved before they are released for production. All design output documents are maintained and controlled.

7.2.2.5 Design reviews, verification and validation [ISO 9001:2008 – 7.3.4, 7.3.5, 7.3.6]

a) At a minimum, every design is verified by holding and recording design reviews. When required by the customer, qualification tests and demonstrations are conducted on First Article Samples prior to full rate production. For new products, and when there is no experience with similar products, prototypes are built and tested.

7.2.2.6 Design changes [ISO 9001:2008 – 7.3.7]

a) Design changes for documents or drawings under Relia-Tek configuration control or in the development stage and under Version Control for documents or drawings under customer configuration control are initiated using a Document Change Notice (DCN) system. Drawings under customer configuration control that have been baselined and require Class I or Class II Engineering Change Proposal (ECP) approval prior to design change are documented with a

Notice of Revision (NOR). Requests for engineering changes are evaluated, and are recommended or rejected, by Engineering, Production and Quality Assurance, and/or other designated personnel as applicable prior to initiating a DCN or NOR. The DCN and ECP/NOR provide details for the rationale for design change and any material or other cost effectivity of the change for in-process or delivered product as well as the "From/To" information for documenting the change. For "ECP baselined" customer configuration control drawings, the ECP must be approved prior to incorporating the NOR changes to the drawing.

Associated Documents

- Operational Procedure RT04-OP-01: Document Control
- Operational Procedure RT07-OP-05: Design Control
- Work Instruction RT07-WI-05-01: Drawing Format and Preparation Guidelines

7.4 Purchasing [ISO 9001:2008 – 7.4]

7.4.1 General Policy

Relia-Tek evaluates its suppliers and purchases only from those that can satisfy quality requirements. Quality performance of suppliers is monitored and evaluated. Purchasing documents clearly and completely describe ordered products, including quality requirements. Purchasing documents are reviewed and approved prior to release. Purchased products are verified before they are used or shipped.

7.4.2 Procedural Policies

7.4.2.1 Supplier evaluation [ISO 9001:2008 – 7.4.1]

a) Any vendor that has not been issued an approved vendor status in Relia-Tek's computer system is classified as a new vendor. When a purchase request is made for products or services from a vendor who is not on the Approved Vendor List, purchasing personnel place the vendor onto the vendor list in the computer system when issuing the Purchase Order (mark with "New Vendor" designation). The Purchase Order specifies the vendor is new and requires special attention at the time of receiving.

b) New vendors' products are required to comply with a more stringent evaluation under Operating Procedure RT07-OP-08, Receiving Inspection. Those new vendors who supply products that require only a general inspection (1st stage) will be placed on the Approved Vendor List only after inspection has been completed and receiving personnel return the Purchasing copy of the Purchase Order to the Purchasing Department. New vendors supplying products which require a 2nd stage inspection per Work Instruction, RT07-WI-08-01, Receiving QA Inspection Control Plan, will be placed on the Approved Vendor List only after inspection has been completed and receiving personnel return the Purchasing copy of the Purchase Order to the Purchasing Department. A supplier assessment must also be completed and recorded within the computer system per Operational Procedure RT07-OP-06, Initial Supplier Assessment.

c) Subcontractors' products are also required to comply with Operating Procedure RT07-OP-08, Receiving Inspection. In addition, a supplier assessment must also be completed and recorded within the computer system per Operational Procedure RT07-OP-06, Initial Supplier Assessment. After all criteria have been met and documented, a new subcontractor may be added to the Approved Supplier List with agreement from the Purchasing, Quality Assurance and Engineering functions.

d) New vendors who are qualified and placed on the Approved Supplier List will be expected to comply with Work Instruction RT07-WI-06-01, Ongoing Supplier Assessment.

7.4.2.2 Supplier Quality Performance Monitoring [ISO 9001:2008 – 7.4.1]

a) Quality performance of suppliers is monitored. Suppliers showing inadequate performance may be asked to implement corrective actions, and be downgraded to the PROVISIONAL rating. If the requested corrective actions are not implemented and there is no improvement, the supplier is further downgraded to the NOT APPROVED rating and is discontinued. Records of suppler monitoring and reevaluations are maintained. The system for monitoring suppliers is defined in Work Instruction RT07-WI-06-01, On-going Supplier Assessment.

7.4.2.3 Approved Supplier List [ISO 9001:2008 – 7.4.1]

a) Purchasing maintains an approved supplier list. Orders may only be placed with suppliers on the list. For initial order placement, an **Approved Supplier List** has been populated with preferred suppliers based on past history and product type. Once an Initial Supplier Assessment is deemed acceptable on material receipts, the supplier remains on the **Approved Supplier List** unless schedule or quality anomalies outside purchase requirements are witnessed. See 7.4.2.2.

7.4.2.4 Purchasing information [ISO 9001:2008 – 7.4.2]

a) Purchasing documents are prepared by the Purchasing department. The documents clearly and completely describe ordered products, including product identification and quality requirements. The Purchasing Manager reviews and approves all purchasing documents prior to release.

b) The preparation, review, and approval of purchasing documents are explained in Operating Procedure RT07-OP-07, Purchasing.

7.4.2.5 Verification of purchased product [ISO 9001:2008 – 7.4.3]

a) Purchased products are inspected by receiving. This includes verification of product identity and quantity, visual inspection and, where applicable, verification that all requested certificates and quality records are available. Designated products are further inspected or tested by Quality Control (QC) personnel.

b) QC inspection or testing may not be necessary when products are supplied with records or certificates demonstrating conformity; or when the supplier is qualified based on their quality system certification or supplier audits, and a satisfactory quality performance history. Normal

sampling of received product for Approved Supplier's without supplier inspection data shall be conducted in accordance with ANSI/ASQ Z1.4, Sample Procedures and Tables for Inspection by Attributes. One witnessed failure outside the requirements from the sample lot, requires a 100% inspection of the entire lot received.

c) Quality Assurance is responsible for selecting appropriate methods for purchased product verification and acceptance. Operational Procedure RT07-OP-06, Initial Supplier Assessment; Work Instruction RT07-WI-06-01, On-going Supplier Assessment; and Operational Procedure 07-04-03, Receiving Inspection set forward rules for selecting product verification methods and for performing receiving and QC inspections.
d) When verification of purchased product is to be performed at supplier's premises, purchasing documents shall specify the intended verification arrangements and method of product release.

Associated Documents

- Operational Procedure RT07-OP-06: Initial Supplier Assessment
- Work Instruction RT07-WI-06-01: On-going Supplier Assessment
- Operational Procedure RT07-OP-07: Purchasing
- Operational Procedure RT07-OP-08: Receiving Inspection
- Work Instruction RT07-OP-08-01: Receiving QA Inspection Control Plan

7.5 Operations and Production [ISO 9001:2008 – 7.5]

7.5.1 General Policy

Product and process information and appropriate work instructions are established and are communicated to relevant personnel. Operations and production processes are monitored and controlled, and are validated where appropriate. Machines and equipment used in production and for monitoring and measurement activities are maintained. Methods for product release and delivery are defined.

Materials, components, parts, subassemblies, and finished products are identified. When required, traceability of materials and processes is recorded and maintained. Inspection and test status of product is identified to ensure that only product that has passed the required inspections is used, installed, or dispatched.

Customer-supplied products are normally controlled in the same manner as are purchased products. Customer-owned tools, equipment, software, or other property are marked to indicate ownership. Loss, damage, or unsuitability of a customer's product is recorded and reported to the customer.

Appropriate handling, storage and preservation methods are implemented to prevent product damage or deterioration. Receipt and dispatch to and from storage areas are controlled. The condition of products in stock is regularly assessed. Product packaging materials and methods are specified and controlled.

7.5.2 Procedural Policies

7.5.2.1 Operations Control [ISO 9001:2008 – 7.5.1]

a) Product and process specifications [ISO 9001:2008 – 7.5.1a]

1) Information specifying product characteristics is communicated to production in the form of drawings, specifications, samples, instructions, work orders, and product specific templates and other tooling. This information is controlled in accordance with Operational Procedure RT04-OP-01, Document Control. Engineering, Production and Quality Assurance determine the scope, form, and distribution of product specifications.

2) Product and process information required by process operators is communicated through the work order or is included in work instructions. Engineering drawings and specifications may be enclosed with the work order to facilitate assembly and inspection. Operational Procedure RT07-OP-04, Process Control, explains how to establish and use these documents.

b) Work instructions [ISO 9001:2008 – 7.5.1b]

1) Work instructions and workmanship standards may be in the form of manuals, procedures, sheets, posted signs, or samples. They provide instruction for performance of a process, operation or task. The need for work instructions is evaluated on the basis of criticality, importance and complexity of the process; the ability to verify results of the process; operator qualifications; and history of quality problems associated with the process. Workmanship standards are provided when acceptability of the process output can only be determined by comparison with a standard sample.

2) Operational Procedure RT07-OP-04, Process Control, specifies criteria for determining when work instructions are needed, and provides guidelines for issuing, authorizing and controlling work instructions.

c) Equipment maintenance [ISO 9001:2008 – 7.5.1c]

1) Key process equipment, machines, hardware, and software are regularly maintained in accordance with maintenance plans specified by equipment manufacturers or departmental managers responsible for the equipment. Requirements for the maintenance of production equipment are specified in Operational Procedure RT07-OP-04, Process Control.

d) Measuring and monitoring equipment [ISO 9001:2008 – 7.5.1d]

1) Requirements for measuring and monitoring equipment are determined by Production and Quality Assurance. This is in accordance with process control and product verification programs defined in product realization planning (refer to Section 7.1 of this manual).

2) Control system for measuring and monitoring equipment is defined in Operational Procedure RT07-OP-03, Inspection Measuring & Test Equipment.

e) Process monitoring and control [ISO 9001:2008 – 7.5.1e]

1) Processes are monitored and controlled through variety of approaches, activities and techniques. The system is designed to control:

- Information, material and operator input into the process;
- Technology, tools and equipment used;
- Process environment and performance; and
- Process output.

Process monitoring activities are further defined in Section 8.2 of this manual.
Activities related to process control are defined in Operational Procedures RT07-OP-04, Process Control, RT08-OP-03, Statistical Techniques, and the specific Work Instructions, Method Sheets, and Manufacturing and Inspection Control Plans.

f) Product release and delivery [ISO 9001:2008 – 7.5.1f]

1) Products are released for delivery only after all specified activities have been satisfactorily completed and conformity of the product has been verified. Operational Procedure RT07-OP-11, Final Inspection, defines the system for final product verification and release.

7.5.2.2 Validation of Processes [ISO 9001:2008 – 7.5.2]

a) Processes where the resulting output cannot be verified by subsequent measurement or monitoring are designated as special processes.

b) Production and Quality Assurance are responsible for identifying, validating, and documenting special processes. Where applicable, Engineering may assist with establishing validation specifications and testing of samples.

c) Special processes are validated and controlled by applicable methods, such as destructive testing of product samples, equipment and personnel qualification, and work instructions and process procedures.

d) Production and Quality Assurance are responsible for selecting and implementing appropriate process validation and control measures for each special process. At a minimum, all special processes are documented in work instructions.

e) Special process records are established and maintained as appropriate. Depending on the control measures implemented, these records may include process qualification and validation reports, equipment qualification and maintenance records, SPC data, first article inspections and tests, operator qualification and training records, and so forth.

7.5.2.3 Identification and Traceability [ISO 9001:2008 – 7.5.3]

a) Product identification

1) Purchased products are identified with unique numbers, codes, or names. The identification is the same as, or is cross-referenced with, the designations used in drawings, specifications, bills of materials, parts lists, purchase orders, etc. Purchased products are identified by marking, labeling, or tagging the products or their packaging, or by identification of the area where the products are held.

2) During all stages of production, products are usually identified by work orders and other documents that accompany them through the production cycle. Parts and components may also be identified by labels or tags, or the containers in which they are held.

3) Final products are identified by their name and part number, which is labeled or marked on the products and/or is printed on the primary product packaging.

4) Rules and activities related to identification of products are governed by Operational Procedure RT07-OP-13, Product Identification and Traceability. Additional relevant procedures are: RT07-OP-04, Process Control, RT07-OP-08, Receiving Inspection, RT07-OP-11, Final Inspection and RT07-OP-16, Packaging and Delivery.

b) Traceability

1) When required by contract, purchase order, laws and regulations, or voluntary standards traceability is implemented to the extent specified. Traceability may also be implemented for internal reasons, to facilitate corrective action.

2) As required, traceability may apply to materials, components, parts, production processes, environmental conditions, inspection and testing, and personnel responsible for processing and verification of products. The scope of traceability is documented in product manufacturing specifications or the production work order.

3) Activities related to establishment and maintenance of traceability are regulated by Operational Procedures RT07-OP-13, Product Identification and Traceability, and RT08-OP-04, Control of Non-conforming Product.

c) Inspection status identification

1) Following every inspection or test, products are identified to indicate whether they have passed or failed the inspection. This is to prevent nonconforming product from being used or dispatched. Physical location of product can only be used as inspection status identification when the location is designated and contained, and in automated production transfer processes.

2) QC inspectors, receiving and production personnel authorized to carry out inspections and testing are responsible for identifying product inspection status. All personnel handling products are responsible for maintaining the identification.

3) Products that have passed the receiving inspection are moved to the material stockroom or designated material staging areas in production. Where intermingling with other product is a possibility, the inspected items are also appropriately tagged or labeled.

4) Status of an in-process inspection is usually identified by a sign-off in the work order accompanying the product. The status may be also identified by tagging or labeling, or holding products in designated containers.

5) Products that pass the final inspection are placed in the finished product area that is designated and used only for this purpose. In addition, finished products are identified as ACCEPTED, and their release is signed off in the work order on the line where the final inspection is called out.

6) Products that fail any inspections or tests are identified as REJECTED, and are segregated and/or quarantined. Whenever a nonconforming product is identified, the nonconformity is documented using a product nonconformity report

7) Detailed instructions on how to identify conforming and nonconforming products are provided in Operational Procedures RT07-05-06, Inspection and Test Status, and Procedure 08-03-01, Control of Nonconforming Product

7.5.2.4 Customer Property [ISO 9001:2008 – 7.5.4]

a) Receiving

1) Customer-supplied products are received and inspected following the same procedure that applies to purchased products, Operational Procedure RT07-OP-08, Receiving Inspection. In the event the supplied products fail receiving inspection, or are not suitable for any other reason, the customer is contacted.

b) Marking, storage, and handling

1) Marking, storage, handling, and preservation of customer supplied products follow the same procedures that apply to purchased products. The applicable procedures are RT07-OP-13, Product Identification and Traceability; RT07-OP-14, Product Handling and; RT07-OP-15, Storage and Preservation.

2) Customer-owned tooling and returnable packaging are permanently marked so that ownership of each item is visually apparent.

3) Customer's software, documents, and other intellectual property are protected to the same extent, as would Relia-Tek's internal documents of similar content, unless there are contractual requirements for special measure to protect customer's intellectual property.

c) Special requirements

1) When specified in a contract or purchase order, special handling instructions from customers will take precedent over the company's standard procedures.

d) Loss or damage

1) Customers are contacted in the event of loss, damage, deterioration, or unsuitability of their products.

7.5.2.4 Preservation of Product [ISO 9001:2008 – 7.5.5]

a) Product handling and preservation

1) Production is responsible for product handling and preservation; and in particular for ensuring that containers holding products are suitable and are in good condition, that equipment used for internal transportation of products is well maintained and is properly operated, and that products are adequately protected during production and storage. Operational Procedures RT07-OP-14, Product Handling and RT07-OP-15, Storage and Preservation, describe in detail how these policies are implemented.

b) Storage

1) Stockrooms and storage, staging and holding areas are controlled by Material Control. Only products that are properly identified and that have passed required inspections are authorized to enter and leave the stockrooms. Periodically, the stockrooms are inspected to assess the condition of stock.

2) When special storage conditions are specified (for example, temperature or humidity), products are stored in special rooms, boxes, or containers where the specified conditions can be continually maintained. These special conditions are monitored to ensure that they are maintained without interruption and that the product is not compromised at any time.

3) Products with limited shelf life are identified with expiration dates. These perishable products are also rotated in the stockroom to ensure that the oldest product is used first.

4) Material and finished product stockrooms are controlled using an inventory management system. The system can report available stock quantities, product location, and turn-over times. The system is used to optimize and minimize inventory levels.

5) Operational Procedure RT07-OP-15, Storage and Preservation, governs the operation of stockrooms and storage, staging and holding areas.

c) Packaging and labeling

1) Primary packaging are boxes, bags or other packaging in which products are presented to the end-users.

2) Secondary packaging are cardboard boxes, crates, or other additional packaging intended to contain and protect products for shipping and transportation.

3) Primary packaging and labeling operations are controlled following the same policies and procedures that apply to production operations and processes. Product packaging and labeling are defined in drawings, specifications and artwork. These documents are issued and controlled in the same manner as other engineering documents. When appropriate, personnel involved with these processes are provided with work instructions and/or special training.

4) Shipping department is responsible for establishing specifications for secondary packaging and labeling. The specifications are compatible with requirements of commonly used carriers and for intended means of delivery (ground, sea, air). Packaging specifications are documented in drawings, written standards, and/or packaging instructions. Packaging specifications are maintained and controlled by Shipping.

5) Packaging and labeling activities are governed by Operational Procedure RT07-OP-16, Packaging and Delivery.

d) Shipping and delivery

1) Shipping of finished products is initiated by the shipping order. The order identifies the shipping consignee address, shipping due date, products to be shipped, labeling requirements, and transportation mode or carrier. Before products are dispatched, the shipping supervisor verifies that the shipment contains the same products and quantities as specified in the shipping order, and that packaging and labeling conform to customer and/or carrier requirements. Only orders that have been verified and signed off by the shipping supervisor can be loaded for shipment.

2) Activities related to shipping and delivery operations are regulated by Operational Procedure RT07-OP-16, Packaging and Delivery.

Associated Documents

- Operational Procedure RT07-OP-03: Inspection, Measuring & Test Equipment
- Operational Procedure RT07-OP-04: Process Control
- Operational Procedure RT07-OP-08: Receiving Inspection
- Operational Procedure RT07-OP-10: In-process Inspection
- Operational Procedure RT07-OP-11: Final Inspection
- Operational Procedure RT07-OP-12: Inspection and Test Status
- Operational Procedure RT07-OP-13: Product Identification and Traceability

- Operational Procedure RT07-OP-14: Product Handling
- Operational Procedure RT07-OP-15: Storage and Preservation
- Operational Procedure RT07-OP-16: Packaging and Delivery
- Operational Procedure RT08-OP-04: Control of Non-conforming Product

7.6 Control of Monitoring and Measuring Equipment [ISO 9001:2008 – 7.6]

7.6.1 General Policy

Appropriate measuring and monitoring instruments are maintained and selected to ensure that measurement capability is consistent with the measurement requirements. Equipment used for assuring product conformity is calibrated using calibration standards traceable to the national standard. Calibration status of measuring equipment is identified with calibration stickers. Measuring equipment is properly maintained and its placement and use are controlled.

7.6.2 Procedural Policies

7.6.2.1 Controlled and uncontrolled equipment

a) The scope of the calibration control system extends to the measuring and test equipment, comparative reference hardware (such as gauges and templates), and test software used for:

- Setup and monitoring of production processes;
- Monitoring of environmental conditions;
- Verification of product conformity; and
- Operations where defined accuracy of a measurement is required to assure product conformity.

b) Equipment used for other purposes may be exempted from calibration. Such equipment is labeled with stickers warning that it is not calibrated. Uncontrolled measuring equipment is prohibited in QC inspection areas.

7.6.2.2 Measurement identification and selection of equipment

a) Identification of measurements to be made and the tolerance of the measured characteristics are documented in control plans and/or in product drawings and specifications.

b) Gauges, instruments, and other measuring and monitoring equipment are selected on the basis of their capability to provide the necessary accuracy of the measurement. Quality Assurance is responsible for selecting appropriate measuring and monitoring equipment.

7.6.2.3 Equipment calibration and maintenance

a) Quality Assurance is responsible for calibrating and maintaining measuring and monitoring equipment. All active equipment is inventoried in a controlled list, indicating equipment calibration status and location.

b) Measuring equipment is calibrated using written instructions, unless calibration is simple and obvious. Only calibration instruments and standards having known relationship to the nationally recognized standards are used for calibrating measuring and test equipment.

c) Calibration is recorded in a calibration certificate and the calibrated equipment is labeled with a calibration sticker.

d) Calibration-related activities are regulated by Operational Procedure RT07-OP-03, Inspection Measuring and Test Equipment.

7.6.2.4 Validation of software

a) In-house developed inspection, test, and monitoring software is validated before it is used for product assurance or verification. Commercial software is purchased with validation certificates where available. Software is revalidated or recertified when conditions for which it was initially validated are materially changed.

Associated Documents

- Operational Procedure RT07-OP-03: Inspection, Measuring and Test Equipment

SECTION 8 - MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 Planning of Monitoring and Measurement [ISO 9001:2008 – 8.1]

8.1.1 General Policy

Measurement and monitoring activities required to assure product conformity, and to achieve continual improvement, are planned and defined. When applicable, statistical techniques are used for analyzing measurement data.

8.1.2 Procedural Policies

8.1.2.1 Planning

a) Measurement and monitoring activities to assure and verify product conformity are defined in engineering specifications and drawings, production work orders, inspection and testing procedures, and process control procedures. These activities are further defined in this manual in Section 8.2, Measurement and Monitoring, and in several operational procedures referenced at the end of this section.

b) The effectiveness of the quality system is monitored by internal audits and by measuring quality performance and customer satisfaction. Results of these activities are reported to the top management and are used to identify opportunities for improvement. Activities related to internal audits and to measuring customer satisfaction and quality performance are further defined in this manual in Sections 8.2.

8.1.2.2 Statistical techniques

a) Statistical techniques may be applied to:

- Testing and validation of designs;
- Set up of process equipment;
- Testing and validation of processes;
- Control of process stability and performance (SPC);
- Establishment of sampling plans for inspections and testing;
- Evaluation of measurement systems; and
- Analysis of quality performance and other company-level data.

b) Departmental managers are responsible for identifying the need for using statistical techniques in their departments and in other activities for which they are responsible. Quality Assurance may be called upon to assist other departments in selecting and documenting specific techniques. Operational Procedure, RT08-OP-03, Statistical Techniques, provides further guidance.

Associated Documents

- Operational Procedure RT07-OP-08: Receiving Inspection

- Operational Procedure RT07-OP-10: In-process Inspection
- Operational Procedure RT07-OP-11: Final Inspection
- Operational Procedure RT08-OP-01: Customer Satisfaction
- Operational Procedure RT08-OP-03: Statistical Techniques
- Operational Procedure RT08-OP-05: Internal Audits

8.2 Monitoring and Measurement [ISO 9001:2008 – 8.2]

8.2.1 General Policy

Customer satisfaction is the principal objective of the quality system, and the level of customer satisfaction is the most important measure of the effectiveness of the system. Customer satisfaction is measured by collecting and analyzing direct customer feedback, and by measuring secondary indicators of customer satisfaction. Customer satisfaction data is used by the top management to identify opportunities and priorities for improvement.

All activities and areas relevant to the quality system are audited at least once a year. Audits are scheduled on the basis of the status and importance of the activity. Internal auditors are independent of those having direct responsibility for the audited activity. Identified nonconforming conditions are brought to the attention of the responsible managers and corrective actions are implemented in response to audit findings.

Quality system processes are monitored to ensure that they achieve planned results. Relevant product characteristics are measured through inspections, tests, and other product verification activities, as specified in control plans. Evidence of product conformity is recorded. Products are released for delivery only after all specified activities have been satisfactorily completed and verified.

8.2.2 Procedural Policies

8.2.2.1 Customer Satisfaction [ISO 9001:2008 – 8.2.1]

a) General

1) Sales/Marketing is responsible for developing suitable indicators of customer satisfaction, and for defining methods for collecting and analyzing the pertinent information.

2) Information and data pertaining to customer satisfaction are collected from several sources. Specifically, these are:

- Customer feedback and surveys,
- Awards and recognitions,
- Product returns and warranty claims, and
- Repeat customer rates.

3) Operational Procedure RT08-OP-01, Customer Satisfaction, defines the system for collecting and analyzing the pertinent information and data, and for reporting results to the top management.

b) Customer feedback and surveys

1) Customer complaints, spontaneous expressions of satisfaction, and other unsolicited customer feedback are collected and processed by the Customer Service department. These activities are defined in Operational Procedure RT07-OP-17, Customer Feedback and Complaints. The resulting data is periodically analyzed by the Customer Service manager, and is presented and discussed at management review meetings.

2) Sales/Marketing conducts quarterly customer satisfaction surveys. Survey results are compiled and analyzed, and are combined with customer satisfaction data for compatible aspects of products and services. Conclusions are presented and discussed at management review meetings.

c) Awards and recognitions

1) Relia-Tek presents its products at conferences, competitions, fairs, and for independent evaluations and assessments. It also encourages customers to rate its performance, and seeks to participate in customer's award and recognition programs. These recognitions and ratings are considered as an important input into determining customer satisfaction.

d) Product returns and warranty claims

1) Information about the rate of product returns and warranty claims is extracted from quality records. Results and trends are reported and analyzed at management review meetings

e) Repeat customers

1) Sales records are periodically analyzed to identify repeat customers and track their ordering frequencies and patterns. The ratio of repeat customers is one of the most important indicators of customer satisfaction. Statistics on repeat customers frequencies and trends are presented and discussed at management reviews.

8.2.2.2 Internal Audit [ISO 9001:2008 – 8.2.2]

a) Planning and scheduling

1) The Audit Coordinator establishes an internal audit plan and schedule in accordance with Procedure RT08-OP-05, Internal Quality Audits. Every activity and area is audited at least once a year. Selected activities are audited more frequently, depending on their importance and quality performance history.

b) Audit team and preparation for audit

1) Only personnel independent of the audited activities are assigned to conduct internal audits. Normally, Quality Assurance leads the audit team except when QA activities are being audited. Audits of QA activities are usually conducted by Engineering.

2) Auditors prepare for audits by reviewing applicable standards and procedures, analyzing quality records, and establishing questionnaires and checklists. Selection of auditors and preparation for the audit are explained in Procedure RT08-OP-05, Internal Quality Audits.

c) Conducting the audit

1) Conducting the audit, auditors seek objective evidence indicating whether the audited activities comply with the requirements of the documented quality system and ISO 9001:2008, and whether the quality system is effective. The evidence is collected by observing activities, interviewing personnel, and examining records.

2) Nonconforming conditions are documented and recorded using the audit nonconformity report form. A model of the form and instructions on how to use it are provided in Operational Procedure RT08-OP-05, Internal Quality Audits. Corrective action requests initiated through the internal audit process are covered by Operational Procedure RT08-OP-06, Corrective Action.

3) Audits are conducted in a way that minimizes disruption of the audited activities.

d) Corrective action and follow up

1) When nonconforming conditions are identified, the manager responsible for the affected area or activity is requested to propose and implement a corrective action. Implementation and effectiveness of the action are verified by a follow-up audit. The corrective action system outlined in Operational Procedure RT08-OP-06, Corrective Action is for monitoring and recording the implementation of the corrective actions.

e) Reporting

1) When the auditing cycle is completed, all nonconformity reports established during the cycle are compiled and analyzed, and are presented at the management review meeting.

8.2.2.3 Monitoring of Quality System Processes [ISO 9001:2008 – 8.2.3]

a) Process monitoring

1) Quality system processes are monitored by variety of approaches and techniques, as appropriate for a particular process and its importance. These include:

- Conducting internal audits of the quality system;
- Monitoring trends in corrective and preventive action requests;
- Analyzing product conformity and other quality performance data and trends;

- Measuring and monitoring customer satisfaction.

b) Response Actions

1) When a quality system process does not conform to requirements, Quality Assurance may request the manager responsible for the process to implement a corrective or preventive action, in accordance with Operational Procedures RT08-OP-06, Corrective Action or RT08-OP-07, Preventive Action.

8.2.2.4 Monitoring of Quality System Processes [ISO 9001:2008 – 8.2.4]

a) Product verification

1) Inspection and testing program for a product is defined in various types of documents, such as product drawings and specifications, production work orders, purchasing documents, inspection and testing procedures, and control plans. Documents defining the inspection and testing program for a product are collectively referred to as control plans. Section 7.1 of this manual defines the process for establishing control plans.

2) **Verification of purchased produc**t: All purchased products are subjected to a visual inspection by receiving, and then some designated products are subjected to a more detailed and technical QA inspection. Operational Procedure RT07-OP-08, Receiving Inspection, sets forward detailed rules for performing receiving and QA inspections.

3) **In-process inspections**: In-process inspections may be in the form of first article inspections, operator or QA inspections, continuous product verification by automated inspection equipment, or statistical process control (SPC). The focus is on defect prevention rather than detection. In-process inspection activities are regulated by Operational Procedures RT07-OP-10, In-process Inspections, and RT08-OP-03, Statistical Techniques.

4) **Final inspection**: Finished products are subjected to the final QA inspection. First, inspectors verify that all specified receiving and in-process inspections have been carried out satisfactorily. Then they perform the remaining inspections and tests necessary to complete the evidence of product conformity. Only products that pass the final inspection can be shipped. Procedure RT07-OP-11, Final Inspection, regulates these activities.

b) Inspection, test and monitoring records

1) Results of inspections and tests are recorded. Rules for establishing records for specific types of inspections are defined in Operational Procedures RT07-OP-08, Receiving Inspection, RT07-OP-10, In-process Inspection, and RT07-OP-11, Final Inspection. Filing and maintenance of inspection records are regulated by Operational Procedure RT04-OP-02, Control of Quality Records.

c) Product release

1) Products are released for delivery only after all specified activities have been satisfactorily completed and conformity of the product has been verified. Only personnel performing final product inspections and tests have the authority to release products. The identity of the person authorizing product release is recorded. Operational Procedure RT07-OP-11, Final Inspection defines specific methods for product release.

Associated Documents

- Operational Procedure RT07-OP-08: Receiving Inspection
- Operational Procedure RT07-OP-10: In-process Inspection
- Operational Procedure RT07-OP-11: Final Inspection
- Operational Procedure RT08-OP-01: Customer Satisfaction
- Operational Procedure RT08-OP-03: Statistical Techniques
- Operational Procedure RT08-OP-05: Internal Quality Audits

8.3 Control of Nonconforming Product [ISO 9001:2008 – 8.3]

8.3.1 General Policy

Nonconforming product is identified, documented, evaluated, and prevented from being used or shipped. Repaired or reworked products are re-inspected. Appropriate actions are taken when product nonconformity is identified after delivery. When appropriate, corrective and preventive actions are implemented to prevent recurrence of identified nonconformities. Product is released for delivery only after all specified activities have been satisfactorily completed and verified.

8.3.2 Procedural Policies

8.3.2.1 Identification and documentation

a) Relia-Tek identifies and documents all product nonconformities, regardless of how insignificant they seem to be or how easily they can be repaired or reworked. Product nonconformity records are invaluable for tracking performance and trends, and for identifying areas where corrective or preventive actions should be implemented.

b) Nonconforming products are documented using a nonconformity report. It describes the nonconformity, documents the disposition decision, and records close-out of follow-up activities (re-inspection, concessions, corrective actions, etc.). The use of nonconformity report and its processing are explained in Operational Procedure RT08-OP-04, Control of Nonconforming Product.

c) To prevent nonconforming products from being used or shipped, the products are marked as REJECTED and are segregated.

8.3.2.2 Nonconformity review and disposition

a) QA inspectors and production supervisors may make the disposition decision for a nonconforming product when it is obvious that the product must be scrapped or regraded, or when it can be repaired by a simple process without affecting its quality or appearance. In all other cases, Quality Assurance together with Production and, when required, Engineering are responsible for making disposition decisions.

b) The disposition decision may be: Rework or Repair, Waiver (Use As-Is), Waiver (With Corrective Action), or Scrap.

c) Detailed rules for nonconformity review, for making the disposition decision, and for recording these activities are provided in Operational Procedure RT08-OP-04, Control of Nonconforming Product.

8.3.2.3 Re-verification of repaired or reworked product

a) Repaired or reworked products are re-inspected in accordance with applicable procedures and instructions (refer to Operational Procedures RT07-OP-08, Receiving Inspection; RT07-OP-10, In-process Inspections; or RT07-OP-11, Final Inspection, as applicable).

8.3.2.4 Product returns and recalls

a) When product nonconformity is detected by the customer after delivery or use has started, the customer is instructed to return the product, or a part, on a return authorization number issued by customer service.

b) When product nonconformity is detected internally after delivery or use has started, customers are informed and instructed what to do with the product. In situations when the nonconformity may create a safety or other hazard, the product may be recalled. Only the President of the company is authorized to make recall decisions.

Associated Documents

- Operational Procedure RT07-OP-08: Receiving Inspection
- Operational Procedure RT07-OP-10: In-process Inspection
- Operational Procedure RT07-OP-11: Final Inspection
- Operational Procedure RT08-OP-04: Control of Non-conforming Product

8.4 Analysis of Data [ISO 9001:2008 – 8.4]

8.4.1 General Policy

Relia-Tek collects, complies and analyzes information and data required for evaluating the suitability and effectiveness of the quality system and for identifying opportunities for continual improvement.

8.4.2 Procedural Policies

8.4.2.1 General

a) Data and information recorded in quality records are compiled and analyzed periodically to determine trends in the performance and effectiveness of the quality system and to identify opportunities for improvement.

b) Quality Assurance is responsible for coordinating these activities, and for reporting conclusions and trends to the top management. This is usually done within the framework of management reviews of the quality system, in accordance with Operational Procedure RT05-OP-01, Management Review.

8.4.2.2 Scope

The following categories of information and data are recorded, compiled and analyzed:

a) Characteristics of processes and products:

- Process performance variation — recorded in process control and evaluated by Manufacturing & Process Engineering.
- Unscheduled machine downtime — recorded in equipment maintenance log and reviewed for trends by Manufacturing Engineering.

b) **Conformance to customer requirements:**

- Scrap, rework — recorded in product yield data and nonconformity reports and reviewed for trends by QA.
- On-time delivery performance — recorded in delivery performance reports and evaluated for trends by Materials Control and executive management.

c) Suppliers

- Supplier quality performance — recorded in subcontractor quality performance files and evaluated for trends by Purchasing and Quality Assurance.

d) Customer satisfaction and dissatisfaction:

- Customer satisfaction levels — recorded in customer satisfaction surveys and evaluated for trends by executive management.
- Customer complaints — recorded in customer complaints and evaluated for trends by executive management.

e) Quality System:

- Effectiveness of training — recorded in training evaluation and evaluated for trends by departmental managers.
- Effectiveness of quality system — recorded in internal audit and evaluated for trends by executive management.

Associated Documents

- Operational Procedure RT05-OP-01: Management Review
- Operational Procedure RT08-OP-02: Continual Improvement

8.5 Continual Improvement [ISO 9001:2008 – 8.5]

8.5.1 General Policy

Relia-Tek deploys a continual improvement philosophy throughout the entire organization. The improvement effort is driven by goals defined in the quality policy and quality objectives. Improvement opportunities are identified by analyzing quality performance data and information. Improvement projects are defined and implemented through the system of corrective and preventive actions and management review actions.

Causes of identified nonconformities are investigated and, where appropriate, corrective actions are implemented to ensure that nonconformities do not recur. Preventive actions are implemented to eliminate the causes of potential nonconformities. Corrective and preventive actions taken are recorded and are followed up to ensure that they have been properly implemented and that they are effective.

8.5.2 Procedural Policies

8.5.2.1 Continual Improvement [ISO 9001:2008 – 8.5.1]

a) Opportunities for improvement

1) Opportunities and priorities for improvement are identified by comparing present quality performance to objectives defined in the quality policy and quality objectives.

2) Quality performance is determined by analyzing information about customer satisfaction, records of product and process nonconformity, results of internal audits, and other data and

information relevant to quality performance. Section 8.4, Analysis of Data, defines the scope and system for collecting and analyzing such information.

3) Quality performance is evaluated by management reviews of the quality system. Where quality performance falls short of a defined objective, the management review identifies specific improvement actions to reach the objective. When a quality objective is reached, the management review may set a new, higher objective in this area and specify new improvement actions for reaching it.

4) This process of facilitating continual improvement though the use of quality policy, objectives, and analysis of data, is defined in Operational Procedures RT08-OP-02, Continual Improvement, and RT05-OP-01, Management Review.

5) In addition to management reviews, departmental managers identify improvement opportunities continually, based on daily feedback form their operations and other activities. Employees are also encouraged to come forward with ideas for improving products, processes, systems, productivity, and working environment. These improvement opportunities are evaluated and prioritized by Quality Assurance and, where appropriate, are implemented though the system of corrective and preventive actions.

b) Implementation of improvement projects

1) Improvement projects are usually implemented through management review actions and through corrective and preventive actions. Where appropriate, improvement projects may be also initiated by management directives, such as policy statements, announcements, memoranda, and so forth.

8.5.2.2 Corrective and Preventive Action [ISO 9001:2008 – 8.5.2, 8.5.3]

a) Preventive versus corrective action

1) Preventive actions are requested and implemented when there are trends of decreasing quality capability and/or effectiveness of the quality system that create a risk for a potential nonconformity. Corrective actions are used when an actual nonconformity is identified.

2) Recognizing this difference, Relia-Tek has separate systems for identifying the need for corrective and preventive actions. However, once the need is identified, a common system is used to process both types of actions. Forms, logs and other documents and records for processing of corrective and preventive actions are the same.

b) Corrective actions

1) The need for corrective action is determined on the basis of identified actual nonconformities. Corrective action requests are typically triggered by such events as a failed inspection, customer complaint and/or product return, nonconforming delivery from a supplier, or a quality system audit finding.

c) Preventive actions

1) The need for preventive action is determined on the basis of information and data regarding capability and performance of processes, product nonconformity rates, postproduction experience feedback, service records, customer complaints, and quality system audit findings. Such information and data are collected and analyzed to detect unfavorable trends that, if not checked, will increase the risk of nonconformities. The system for collecting and analyzing quality performance information and data is defined in Section 8.4 of this manual.

d) Processing of corrective and preventive actions

1) Preventive and corrective actions are initiated, processed and followed up using the CAR (Corrective Action Request) and PAR (Preventive Action Request) systems. The systems documents the unsatisfactory condition and the corrective or preventive action to be taken, and is used to record the verification and closure of the action. Open CARs are reviewed regularly to ensure that the actions are implemented and followed up in a timely manner. Operational Procedures RT08-OP-06, Corrective Action and RT08-OP-07, Preventive Action explain how to use the CAR and PAR system.

e) Continual improvement

1) Continual improvement actions are often defined as corrective and preventive actions. This is especially true for preventive actions. Operational Procedures RT08-OP-02, Continual Improvement, and RT05-OP-01, Management Reviews, explain how the corrective and preventive action system is used for facilitating continual improvement.

Associated Documents

- Operational Procedure RT05-OP-01: Management Review
- Operational Procedure RT08-OP-02: Continual Improvement
- Operational Procedure RT08-OP-06: Corrective Action
- Operational Procedure RT08-OP-07: Preventive Action

Quality Manual Operating Procedure and Work Instruction Section References

Operating Procedure (OP) / Work Instruction (WI)	Description	Section(s)
RT04-OP-01	Document Control	4.1.2.1, 4.2.2.1, 4.2.2.3, 5.5.2.3, 7.5.2.1
RT04-WI-01-01	In-Process Change	4.2.2.3
RT04-WI-01-02	Issuing Documents	4.2.2.3
RT04-OP-02	Control of Quality Records	4.2.2.4, 7.2.2.1, 8.2.2.4
RT05-OP-01	Management Review	5.1.2.4, 5.3.2.4, 5.4.2.1, 5.4.2.4, 5.5.2.3, 5.6.2.2, 6.1.2.2, 6.1.2.3, 6.2.2.4, 8.4.2.1, 8.5.2.1, 8.5.2.2
RT06-OP-01	Training and Awareness	5.5.2.3, 6.2.2.2, 6.2.2.3
RT07-OP-01	Contract Review	7.1.2.1, 7.1.2.3, 7.2.2.1, 7.2.2.2
RT07-OP-02	Customer Feedback and Complaints	5.2.2.2, 7.2.2.2
RT07-OP-03	Inspection, Measuring & Test Eqmt.	6.3.2.2, 7.5.2.1, 7.6.2.3
RT07-OP-04	Process Control	6.3.2.2, 7.5.2.1, 7.5.2.3
RT07-WI-04-01	Standard Op. Proc. Maintenance	6.3.2.2
RT07-WI-04-02	Production Environmental Rqmts.	6.3.2.2
RT07-OP-05	Design Control	7.1.2.1, 7.1.2.3, 7.2.2.1
RT07-WI-05-01	Drawing Format and Preparation Guide	7.2.2.1
RT07-OP-06	Initial Supplier Assessment	7.1.2.3, 7.4.2.1
RT07-WI-06-01	On-going Supplier Assessment	7.1.2.3, 7.4.2.1, 7.4.2.2, 7.4.2.5
RT07-OP-07	Purchasing	7.1.2.3, 7.4.2.4
RT07-OP-08	Receiving Inspection	7.1.2.3, 7.4.2.1, 7.5.2.3, 7.5.2.4, 8.1.2.1, 8.2.2.4, 8.3.2.3
RT07-WI-08-01	Receiving QA Inspection Control Plan	7.4.2.1
RT07-OP-09	Set-up Inspection	7.1.2.3, 7.5.2.3
RT07-OP-10	In-process Inspection	7.1.2.3, 7.5.2.3, 8.1.2.1, 8.2.2.4, 8.3.2.3
RT07-OP-11	Final Inspection	7.1.2.3, 7.5.2.1, 7.5.2.3, 8.1.2.1, 8.2.2.4, 8.2.3.3
RT07-OP-12	Inspection and Test Status	7.1.2.3, 7.5.2.3
RT07-OP-13	Product Identification and Traceability	7.5.2.3, 7.5.2.4
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