

Reliable Technology for Tactical Integration Solutions

Quality Manual

ISO9001:2015

Relia-Tek, LLC
RT-QM-9001
Revision: X4

Approved: H. Jefferson Wood, Engineering Manager *H. Jeff Wood*, 12/6/2020

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Revision Status

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X3	Added Counterfeit Detection	RT-QM-9001 X3	H. J. Wood	8/15/2016
X4	Converted to ISO 9001:2015	RT-QM-9001 X4	H. J. Wood	12/6/2020

1.0 Introduction

The Quality Manual presented herein describes the quality management system in operation at Relia-Tek, LLC (hereinafter referred to as Relia-Tek). 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, including continual improvement and the prevention of nonconformity.

The manual is divided into ten sections modeled on the sectional organization of the ISO 9001:2015 standard. Sections are further subdivided into subsections representing quality system elements or activities and applicable operating Procedures and work instructions.

2.0 Purpose

This manual is prepared for the purpose of defining the company's interpretations of the ISO 9001:2015 international standard, as well as to demonstrate how the company complies with that standard. Additionally, 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.

Relia-Tek values the importance of a Quality Management System (QMS) 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.

3.0 Related Documents

This Quality Manual is supported by the documented information (Operating Procedures) and other process control documents (Work Instructions) that define the Quality System in detail. Specific documents related to each section are available from Relia-Tek's Document Management System. See Appendix A at the end of the quality manual for a list of Operating Procedures and their cross reference to sections herein.

This quality manual document refers to terms and concepts found in ISO 9001:2015, Quality Management Systems—Requirements. This manual and all supporting documents comply with ISO 9001:2015 and ANSI/ISO/ASQ Q9001-2015 Quality Standards with no exclusions.

4.0 Context of the Organization

4.1 Understanding the organization and its context

Relia-Tek reviews and analyzes key aspects of itself and its stakeholders to determine the strategic direction of the company. This requires understanding internal and external issues that are of concern to Relia-Tek and its interested parties per 4.2 below. The identification and determination of context of the organization, needs and expectations of interested parties are performed according to the Management Strategic Planning Procedure.

4.2 Understanding the Needs and Expectations of Interested Parties

The relevant internal and external issues determined per 4.1 above are identified through analysis of risks facing Relia-Tek and its interested parties. Interested parties are those stakeholders who receive our products or services or who may be impacted by them, or those parties who may otherwise have a significant interest in our company. These parties are identified per the Management Strategic Planning Procedure. The information is then used by Top Management to determine the company's strategic direction. This is captured in records of management review, and periodically updated as conditions and situations change.

4.3 Determining the Scope of the Quality Management System

Based on the analysis of the organization and its context (both internal and external issues), interests of stakeholders, and in consideration of its products and services, Relia-Tek has determined the scope of the management system as follows:

Design, manufacturing, installation, servicing, and distribution of cable, wiring harnesses and electro-mechanical assemblies for military use.

The quality system applies to all processes, activities, and employees of the following company locations with the exception that "business processes" such as IT, finance & accounting, and legal activities are out of scope of the QMS.

Relia-Tek Production Facility and Environmental Testing Laboratory locations

Relia-Tek Production Facility
3260 Industry Drive, Suite 5
North Charleston, SC 29418

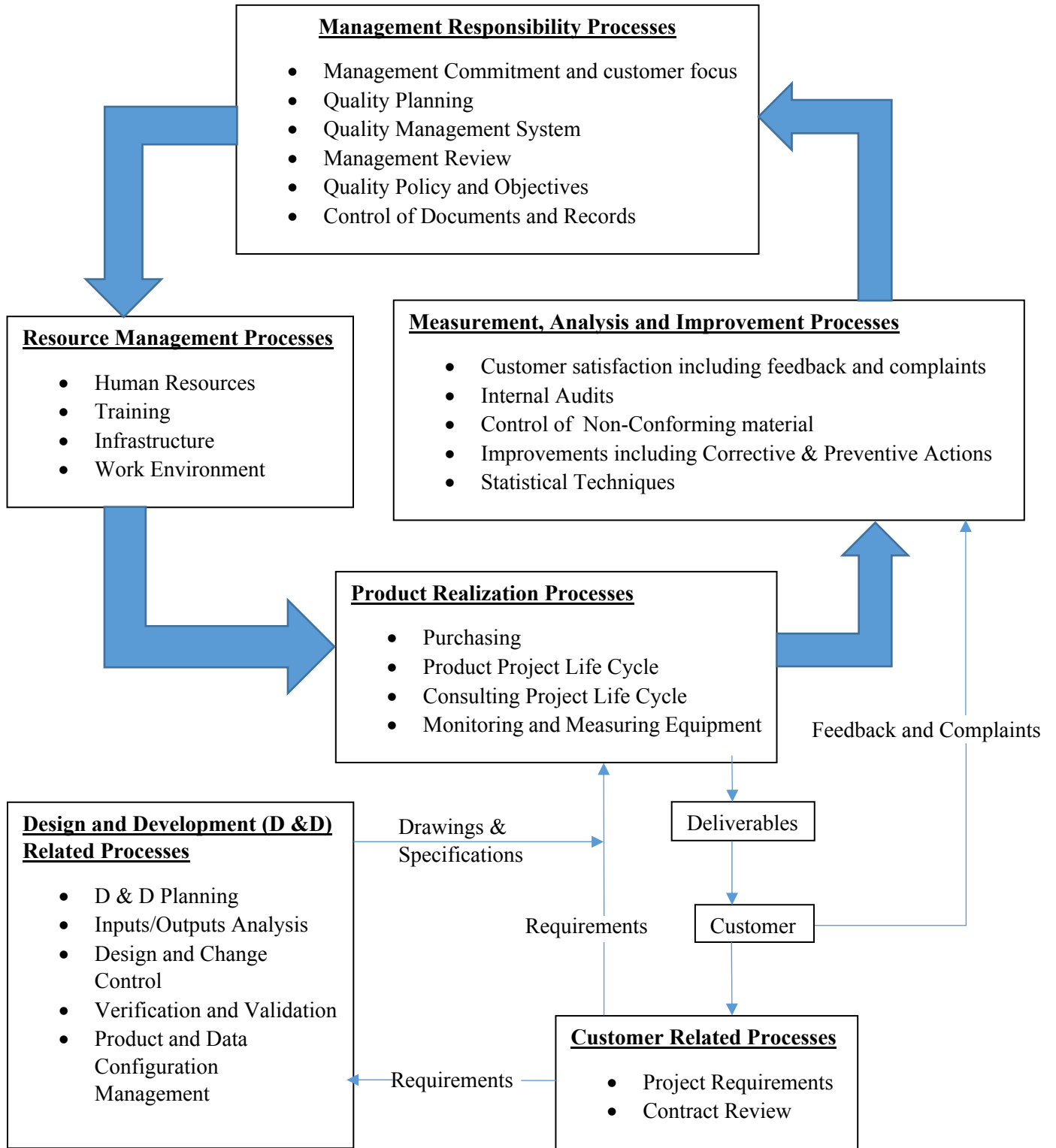
Relia-Tek Environmental Testing Laboratory
44 Wespanee Drive
Charleston, SC 29407

Website: www.relia-tek.com | Phone: 843-471-0259 | Cage Code: 79NB1

4.4 Quality Management System and its Processes

Relia-Tek has established and maintains a Quality Management System (QMS) to ensure consistent delivery of products that conform to specifications, and to promote continual improvement of processes. The system conforms to the requirements of ISO 9001:2015 standard.

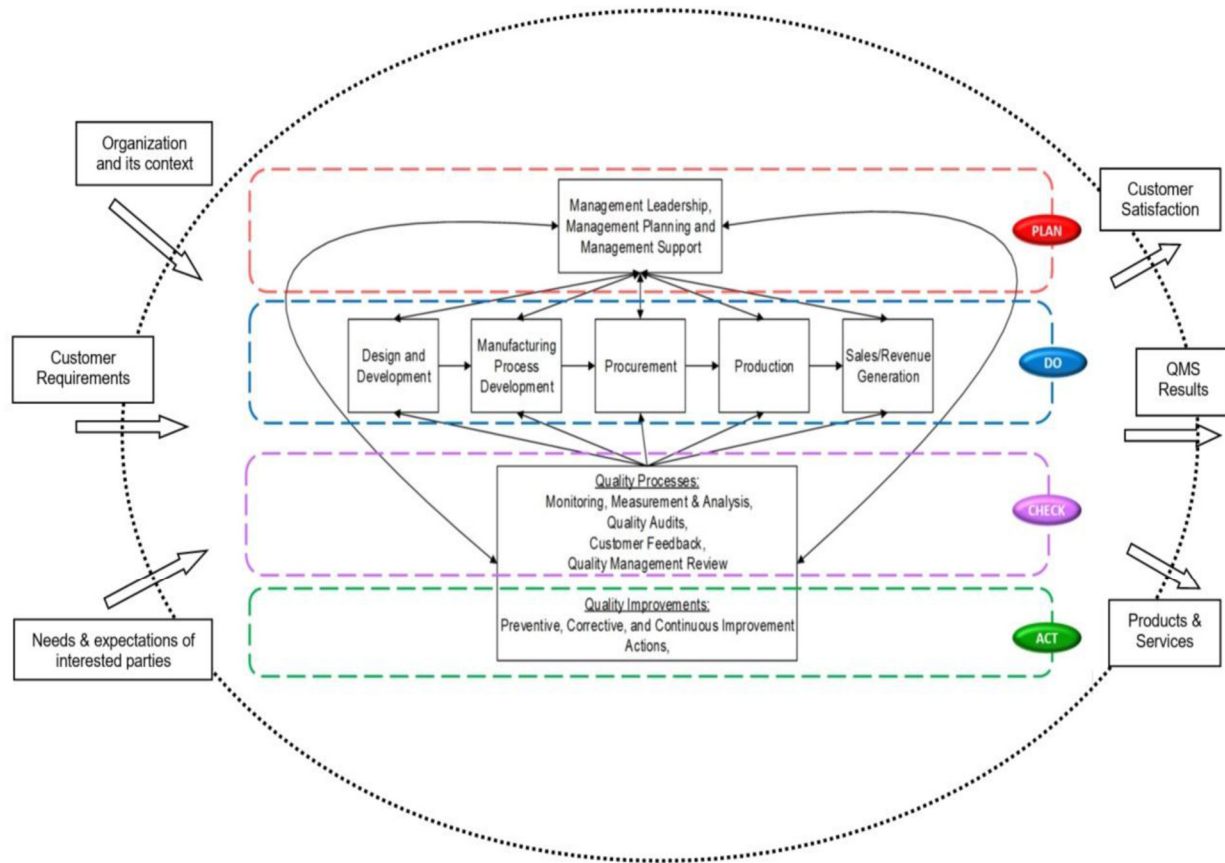
Relia-Tek has adopted a process approach for developing and managing processes and their interactions to achieve planned results consistent with the strategic direction of the company and its Quality Policy. Accordingly, Relia-Tek has determined the processes needed for its QMS and their application through the organization. The sequence of interaction of these processes is illustrated below.



Relia-Tek Quality Management System Overview

Each process can have one or more objectives established for it. Each objective may be supported by a metric, metrics or Key Performance Indicator (KPI) which is then measured to determine the process' ability to meet the quality objective. This is determined by the nature of the process, its impact on products and associated risks. Process measurements and “quality objectives” can be treated as separate concepts but Relia-Tek combines them; i.e., quality objectives are used to control the processes. Additional objectives may be assigned, but these can also be used to measure process effectiveness.

The following diagram illustrates how PDCA (Plan-Do-Check-Act) cycle is applied to Relia-Tek business processes and to its QMS as a whole. The PDCA cycle is an ongoing cycle that drives Relia-Tek towards continual improvement.



Customer requirements, needs and expectations of interested parties, results of organization's self-evaluation (organization and its context) serve as key inputs to Relia-Tek's QMS and its processes. These processes are designed to effectively translate the inputs into enhancing customer satisfaction by delivering conforming products & services and from strengthening QMS through continual improvement.

5.0 Leadership

5.1 Leadership and Commitment

5.1.1 General

Relia-Tek management is committed to the development and implementation of the QMS, as well as to continually improving its effectiveness. All managers are responsible for communicating the importance of meeting customer, applicable statutory, and regulatory requirements on products and services offered. Further, management demonstrates its commitment through the establishment of the Relia-Tek Quality Policy (refer 5.2), by establishing and monitoring quality objectives through the management review process, and by ensuring the availability of resources, consistent with corporate viability, to the quality system. Top Management is responsible for assuring the continued integrity of the QMS in response to significant corporate changes that may occur due to cyclical business conditions.

5.1.2 Customer focus

Relia-Tek management adopts a customer-first approach and is committed to promoting awareness of customer requirements throughout the organization and ensuring customer requirements are determined and met or exceeded with the aim of delighting our customers and enhancing satisfaction. Through its portfolio of products and services, Relia-Tek is focused on delivering significant customer benefits such as improvements in yields, throughput, quality, processes and operational efficiencies that save customers time and expense.

5.2 Policy

Quality Policy captures the overall quality intentions and directions of Relia-Tek as expressed by the Top Management. The policy reflects Relia-Tek's vision and strategy and that is relevant and usable by all employees as a focus for their job. Top Management is responsible:

- to provide a consistent and effective Quality Policy to the organization, allowing and encouraging individual commitment to quality.
- for ensuring that Quality Policy is understood, implemented and maintained at all levels of the organization.
- for communicating the policy to relevant interested parties.

Relia-Tek strives to meet or exceed customer's expectations by adopting the following Quality Policy:

- Drive innovation based upon key customer and market requirements combined with efficient business processes.
- Understand key applications of customers.
- Identify risks, defects and variations early for continuous improvement.
- Design for quality, reliability and process controlled manufacturing to meet or exceed customer requirements.
- Assess and enhance customer satisfaction.
- Continually improve based upon lessons learned and best practices.

5.3 Organizational Roles Responsibilities and Authorities

Top Management will ensure that responsibilities and authorities are defined and communicated within the organization. These are communicated through the combination of defining the organization structure, listing of employees and corresponding position profile. The Top Management assigns roles and responsibilities:

- to ensure and verify that the QMS, as described herein, is established, implemented, maintained and improved;
- to ensure that the QMS conforms to ISO 9001:2015 standard requirements;
- to ensure process owners periodically report to Top Management on the performance and effectiveness of the quality system, including an assessment of the need for improvement and;
- to ensure the promotion of awareness of customer requirements throughout the organization.

6.0 Planning

6.1 Actions to Address Risks and Opportunities

When planning for the QMS, Relia-Tek considers the sources of risk, and opportunities that arise from the context of Relia-Tek, its scope and requirements of interested parties, and how to effectively treat these risks and opportunities.

Relia-Tek considers and manages risk (a negative effect of uncertainty) and opportunity (a positive effect of uncertainty) differently. Risks and opportunities are identified and addressed in order to give assurance that the QMS can achieve its intended results, enhance desirable effects, prevent or reduce undesired effects, and achieve continual improvement. Risks are managed with a focus on decreasing their likelihood, and minimizing their impact. Opportunities are managed to increase their likelihood, and to maximize their benefits. The best appropriate method for managing risks and opportunities shall be determined if they happen to overlap given the situation at hand. This may require methods which both address the negative risk and positive opportunity.

Risks and opportunities are identified and analyzed as part of the Management Strategic Review Process as well as throughout all other activities of the QMS.

Risks and opportunities are managed in accordance with Risk and Opportunity Management Work Instructions. This document defines how risks are managed in order to minimize their likelihood and impact, and how opportunities are managed to improve their likelihood and benefit. Risks in the product design or production processes are managed in accordance with Failure Modes and Effects Analysis (FMEA) Work Instructions.

6.2 Quality Objectives and Planning to Achieve Them

Quality Policy provides the framework for establishing Quality Objectives. Risk and Opportunity analysis drives Quality Objectives to promote improvements. Quality Objectives are defined relevant to Relia-Tek business processes while strategically aligned to the context of the organization. Relia-Tek may utilize its process and product-related objectives as the main quality objectives for the QMS.

6.3 Planning of Changes

Changes to the QMS and its processes are carried out in a planned manner. The organization considers the purpose of the changes and their potential risks; the change effect on the integrity of QMS; the availability of resources to enforce the change; and the allocation or reallocation of responsibilities and authorities.

7.0 Support

7.1 Resources

7.1.1 General

Relia-Tek determines and provides the resources needed to implement and maintain the management system, to continually improve its effectiveness and to enhance customer satisfaction through meeting or exceeding customer requirements. Resource allocation is done with consideration of the capability and constraints on existing internal resources. Resources are allocated according to the priorities established in the management strategic planning process. The adequacy of resources is reviewed and modified during department budget reviews and through the Quality Management Review.

7.1.2 People

Top Management ensures that it provides sufficient staffing for the effective operation and control of the management system and its identified processes.

7.1.3 Infrastructure

Relia-Tek determines, provides and maintains the infrastructure needed to achieve conformity to product and service requirements. Relia-Tek is committed to assuring that the buildings, work spaces, process equipment, and supporting services are adequate to achieve conformity of products and services.

7.1.4 Environment for the Operation of Processes

Relia-Tek provides a clean, safe and well-lit working environment. The Top Management manages the work environment needed to achieve conformity to product and service requirements. Human factors such as social, psychological and physical factors are considered to the extent where they directly impact the quality of Relia-Tek's products and processes. Any work environment aspects which can directly affect process efficiency or product quality are managed through the management system.

7.1.5 Monitoring and Measuring Resources

Inspection, monitoring, measuring and test equipment that is necessary to ensure the performance, quality, and safety of our products is:

- identified,
- controlled,
- maintained, and
- calibrated as required on a periodic basis.

Relia-Tek has established and maintains documented procedure such as Calibration Procedure that describe how monitoring and measuring devices;

- are calibrated and adjusted periodically (or prior to use), against measurement standards traceable to national or international standards; the basis used for calibration/verification shall be recorded when no such standards exist,
- are identified to enable the calibration status to be determined,

- are safeguarded from adjustment that would invalidate the calibration, and
- are protected from damage and deterioration during handling, maintenance and storage.

Records of monitoring and measurement device calibration are maintained as quality records.

Manufacturing Engineering is responsible for establishing and maintaining Procedures related to product-specific equipment that provides validation. Equipment requiring calibration is marked, tagged or labeled in a manner to indicate the equipment identification, current status and next certification or calibration date. Equipment not requiring calibration is plainly marked or labeled to indicate calibration is not required.

Test software is checked at prescribed intervals to prove that it is capable of verifying the acceptability of product. Where appropriate, calibration of instrumentation is performed by a certified external test laboratory, which is accredited and traceable to the National Institute of Standards and Technology (NIST) or equivalent. Where not practicable, the means of calibration will be specified.

Equipment that has accuracy or functional problems is immediately removed from use. When equipment is found to be out of calibration, the Manufacturing Engineering is responsible to develop recovery plans appropriate to the situation.

The Top Management ensures the provision of necessary resources to ensure valid and reliable results where monitoring or measuring is required to verify the conformity of products to requirements.

7.1.6 Organizational Knowledge

Relia-Tek determines the knowledge necessary for the effective operation of its processes and to achieve conformity of products and services. This knowledge is maintained, and communicated to various levels of the organization as necessary. When addressing changing needs and trends, Relia-Tek considers its current knowledge and determines how to acquire or access the necessary additional knowledge to close the knowledge gap.

7.2 Competence

Training is directed towards the development and improvement of work-related skills. The term “training” includes technical and academic education, skills, and experience required or recommended for performance of work to ensure that personnel are qualified to perform tasks. Managers are responsible for setting requirements and recommendations for training, education and experience for their employees as documented in their position profiles. Performance communication between employee and supervisor is done on a regular basis per Performance Communication Procedure that covers performance appraisal, progress, and training needs. The Human Resources Management is responsible for identifying and documenting general training requirements relating to company policy, confidentiality, benefits and employment law and to provide for this training. Department specific training requirements related to products, processes, quality are covered under departmental Procedures. Records of education, training, and experience for individual employees are maintained by the Human Resources Department.

7.3 Awareness

Relia-Tek ensures that persons performing work under its control are aware of the Quality Policy, relevant Quality Objectives, their contribution to the effectiveness of QMS, and implications of nonconformance to QMS requirements.

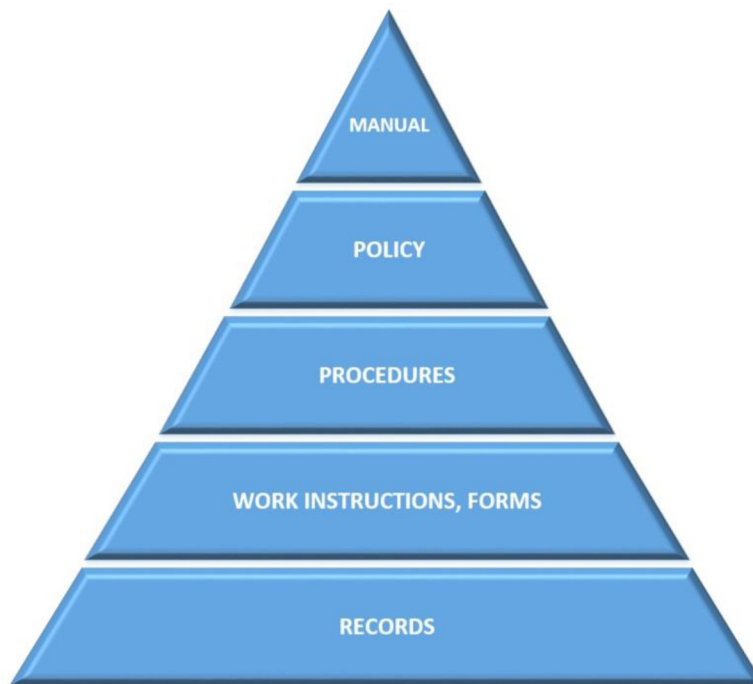
7.4 Communication

Relia-Tek ensures internal and external communication takes place relevant to QMS and its processes. Appropriate communication channels, including on what to communicate to, when, with whom, how and who, are established to address various interested parties.

7.5 Documented Information

7.5.1 General

The Quality System or QMS is documented at multiple levels to ensure the planning and building of quality into Relia-Tek's products, processes and services. The hierarchy of documents that govern and implement the Quality System is shown below.



The Quality Manual, which is the top-level document, describes the QMS, scope of the system and the interaction between processes in the system (refer 4.4).

The Quality Policy states the organization's commitment to quality and to continual improvement.

Procedures are Documented Information that directly support the Quality Manual and Quality Policy, providing expanded, process-specific detail relative to the requirements stated in the Manual and the Policy.

Work Instructions and Forms are also Documented Information that are department- or product-specific documents that provide the detail required for individuals to perform their tasks.

Records are Retained Documented Information that can be available in the form of hard copy media, electronic media or other forms. Storage and maintenance of Quality Records are specified in Procedures or Documented Information.

Quality documents are available and structured per ISO 9001:2015 clauses within the Relia-Tek's Document Management system.

7.5.2 Creating and Updating

When Procedures or Documented Information are created and updated, Document Control Procedures specify appropriate guidelines for identifying, describing, formatting, reviewing and approving the document.

7.5.3 Control of Documented Information

All documents changes/ revisions follow the change control process administered by the documentation personnel. Personnel who obtain documents from outside Relia-Tek are responsible for identifying these documents and controlling their distribution.

A revision or change will be considered complete when obsolete material is properly eliminated, marked as obsolete, or moved to Inactive, Superseded, or Obsolete status in electronic Document Management System.

Each department is responsible for removing copies of obsolete documentation from their areas, or for applying suitable identification to obsolete documents if retained for any purpose. Documents must be approved via the designated approval process prior to being authorized for use.

Documents of external origin are identified and their distribution controlled.

The maintenance of quality records or retained documented information is addressed within individual Procedures. Quality records are indexed by their identification numbers or titles unless stated in the procedure.

Quality records are accessible to all Relia-Tek employees unless marked as confidential. Confidential records are only accessible to authorized personnel.

Upon notification that a controlled document has been revised, it is the responsibility of any Relia-Tek employee to remove outdated or obsolete documentation. When obsolete records are destroyed, those considered to be company confidential are shredded. Non-confidential records may be disposed of normally.

Quality records are maintained to demonstrate conformance to specified requirements and the effective operation of the quality system.

All quality records are maintained in legible condition, and are stored and retained in such a way that they are readily retrievable, using facilities that provide a suitable environment to prevent damage, deterioration, or loss.

8.0 Operation

8.1 Operational Planning and Control

Processes have been developed as mentioned in section 4.4 for realization of products and services. These processes are developed, implemented and controlled to set up product requirements and quality objectives for each product; establish processes, documents, and resource requirements specific to the product; delineate verification, validation, monitoring, inspection, and test activities, and; specify records needed as evidence to assure conformance to customer requirements.

Any changes to the operation of these processes are reviewed and controlled to ensure appropriate actions are taken to address any adverse effects.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Relia-Tek has established, documented Procedures for reviewing and communicating product information, order handling, and customer feedback, including complaints, contracts, quotes and orders, and for the coordination of these activities. These contract review procedures apply to standard products, non-standard products, and service contracts.

8.2.2 Determining the requirements related to Products and Services

In preparation for introducing a new product, Relia-Tek follows the process detailed in Product Development Procedures to determine;

- the requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- requirements not stated by the customer, but necessary for specified or intended use, where known;
- statutory and regulatory requirements related to the product, and
- any additional requirements determined by Relia-Tek.

8.2.3 Review of Requirements Related to Products and Services

Relia-Tek reviews product requirements and the reviews are performed proportionate to the product or service provided.

Reviews are conducted prior to Relia-Tek's commitment to supply a product or service to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders).

The review ensures that:

- product requirements are defined;
- contract or order requirements differing from those previously expressed are resolved;
- Relia-Tek has the ability to meet the defined requirements
- Records of the results of reviews and actions arising from reviews shall be maintained.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by Relia-Tek before acceptance.

Where product requirements are changed, Relia-Tek shall ensure that relevant documents are amended, and that relevant personnel are made aware of the changed requirements.

8.2.4 Changes to Requirements for Products and Services

Relia-Tek updates all relevant requirements and documents when the requirements for the products and services are changed, and ensures that all relevant persons are notified.

8.3 Design and Development of Products and Services

8.3.1 General

Relia-Tek has established, implemented and maintains a robust process to support design and development of varying scope and scale. The Product Development Process Procedure describes the processes for the initiation, development, design, verification, validation and release of new product designs.

8.3.2 Design and Development Planning

Product design is planned, controlled, documented and updated per the product development process. Top Management identifies and selects product development projects. Resources are assigned to development projects by functional managers through negotiation with the Project Manager, under the direction of Top Management.

Phase Reviews are held at the end of each phase to assure that the objectives of the phase are complete and planning is completed for the next phase. Technical Reviews are held as called out in the Project Plan. Both types of review follow the Product Development Process Procedure. Customer Reviews may also be held as necessary as part of the project. Risk analysis is performed to identify product, project, and business risks, prioritize their impact on the project, and identify mitigations to those risks.

Identification of the manufacturing controls, processes, equipment, and fixtures are addressed during the product development process and documented accordingly. The required resources are listed in the Project Plan and are updated during each development phase.

The compatibility of the design, the manufacturing process, installation, servicing and inspection and test Procedures are also addressed and identified during the product development process and documented accordingly.

8.3.3 Design and Development Inputs

The identification of customer/market requirements is addressed during the ideation and feasibility phases of the product development process. This phase addresses any high-risk areas and develops a conceptual design and a specification for the project. Product functional and performance requirements including applicable statutory and regulatory requirements are identified, documented, and reviewed for adequacy by the Project Manager and Top Management. The design inputs are captured for the development team in the Product Requirements and Specification Document.

The Project Manager identifies and resolves incomplete, ambiguous, or conflicting requirements.

8.3.4 Design and Development Controls

At appropriate stages, the design is verified to ensure design output matches design input per product specification. Verification measures are recorded. Thoroughness of verification is reviewed in each phase review.

Designs are validated to the established criteria to ensure that product conforms to defined customer or market needs/requirements as defined in the Product Requirements and Specification Document and or supporting project documentation. Completeness of validation is assessed during validation phase review.

8.3.5 Design and Development Outputs

Design output is documented and expressed in data that can be verified against design input requirements. Design output documents are reviewed before release.

Design output:

- meets or exceeds the design input requirements.
- contains or references acceptance criteria.
- provides appropriate information for purchasing, production, and service provisions,
- identifies those characteristics of the design that are crucial to the safe and proper functioning of the product.
- follows the ECO Release process when the product is ready for release.

8.3.6 Design and Development Changes

Changes, modifications, and revisions are controlled through the Document Change Notice (DCN) system. This system identifies, documents, and establishes the appropriate review and approvals for the changes. Document Control is responsible for administering the DCN process, including review, approval, implementation, distribution of DCNs, and maintaining the supporting documentation on Relia-Tek's Document Management System. Document Control is responsible for administration of the Deviation Authorization (DA) process, including review, approval, and distribution.

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General

Relia-Tek has developed and maintains processes to ensure that purchased materials conform to specified requirements. The type and extent of the control applied shall depend upon the effect of the purchased product on subsequent product realization. Purchasing is responsible for maintaining records of potential and currently-approved suppliers. In selecting and approving suppliers (external providers), consideration is taken into the type of product and the impact that the supplier will have on the quality of the final product. Documented Procedures such as Purchasing, Supplier Assessment, detail:

- the processes and criteria used to evaluate and select suppliers,

- the processes and methods used to communicate requirements to suppliers,
- the processes for verifying that supplier materials meet requirements,
- the need for, and the level to which, supplier performance records are maintained and how these records are used in on-going evaluation of supplier performance and
- the systems for identifying, communicating and resolving problems.

8.4.2 Type and Extent of Control

Incoming material/parts are verified according to the appropriate documentation. Verification of incoming material takes into consideration controls exercised by the subcontractor as well as counterfeit detection and avoidance.

When specified by contract/written agreement, Relia-Tek has the right to perform product verification at the source's facility.

When specified by contract/written agreement, our customer or their representative has the right to perform subcontracted product verification at the subcontractor's or our facility. If verification by the customer is performed, Relia-Tek is still responsible for providing acceptable product and the customer is still afforded the right to subsequent rejection.

Documented information such as Receiving Inspection Work Instructions describes the sampling plan and criteria for acceptance. Verification of purchased product is also performed during the build process via in-process inspection and production tests.

8.4.3 Information for External Providers

Purchasing documents clearly describe the product, material, part, or service ordered and the terms and conditions between Relia-Tek and their suppliers.

Purchasing data is reviewed for adequacy of the specified requirements prior to release of the purchase order.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

Manufacturing Engineering is responsible for manufacturing process control and documentation. This documentation includes information that describes the characteristics of the product, and product-specific work instructions. Manufacturing Engineering is also responsible for:

- development and management of appropriate manufacturing and assembly processes;
- maintenance and implementation of suitable infrastructure, equipment for manufacturing, monitoring, and measuring the product;
- process risk assessment and treatment;
- process control guidelines (ex: Control Plan) and
- appointment of competent assemblers.

Validation of new production processes and re-validation of significantly modified production processes will comply with the requirements detailed in Product Development Process Procedure.

Manufacturing Engineering is responsible for validating manufacturing processes, i.e. to demonstrate that processes have the ability to achieve planned results. Validation may include defining criteria for review and approval of processes, approval of equipment and qualification of personnel, use of specific methods and Procedures, record requirements, and re-validation after process changes.

For software distribution, provisions are made in the duplication and distribution process to verify that the software being produced meets specifications.

Where the results of processes cannot be fully verified by subsequent inspection and testing, these processes are carried out by qualified operators and/or undergo continuous monitoring and control to ensure that specified requirements are met.

Identification of any qualification of manufacturing processes, equipment and personnel is addressed and identified during the product development process and is captured in the appropriate project documentation.

Setup inspection, In-process inspection, testing and final inspection is conducted in accordance with the product-specific build procedure to prevent manufacturing anomalies and human error. No product is shipped until all the activities specified in the quality plan and/or documented Procedures have been completed and the associated data and documentation is available and approved. Final inspection is performed by trained personnel to check for any outgoing quality defects.

Customer Service is responsible for providing warranty and post warranty service and support for Relia-Tek products. Customer Service employs technicians who are trained as appropriate, to install, service and support its products. Customer service and support processes are established to install, service and support Relia-Tek products.

8.5.2 Identification and Traceability

Components, parts, and/or assemblies requiring identification and/or traceability are defined in manufacturing Procedures and/or work instructions. The assembly Procedures and test Procedures include provisions to identify the production, inspection and test status. Work in process is identified, where appropriate, by product-specific build Procedures. The Manufacturing group retains traveler documents and/or work orders as quality records.

8.5.3 Property Belonging to Customers or External Providers

In general, customer-supplied product refers to products returned from customers for repairs or loaned system test equipment. Customer Service is responsible for the disposition, routing, and return of customer-supplied product and documentation for loaned equipment. Customer Service establishes and maintains Procedures related to the customer-supplied product system and its operation.

Customer-supplied product is identified by contract, lot number, order number, or other customer-provided product documentation, and is tracked internally by a Return Material Authorization (RMA) number, DD1149 or other property management documentation. Customer-supplied product is appropriately verified as to correctness, quantity, and suitability.

8.5.4 Preservation

To ensure and maintain process and product conformance, Relia-Tek has established Procedures that control product handling, storage, packaging, preservation and delivery. The Operations group establishes, documents, and is responsible for the general requirements and Procedures necessary for handling, storage, packaging, preservation, and delivery.

Preservation is in accordance to contractually agreed or specified company Procedures, which consider the characteristics of the prevailing environment, transportation, and destination.

Preparation for delivery is in accordance with contract requirements, using materials and markings specified. Marking and labeling must be legible and remain intact until delivery.

8.5.5 Post-Delivery Activities

Post-delivery activities are conducted to meet the requirements associated with the products and services. Relia-Tek considers statutory and regulatory requirements; the potential undesired consequences associated with the products and services; the nature, use and intended lifetime of the products and services, customer requirements and customer feedback to determine the extent of post-delivery activities.

8.5.6 Control of Changes

To ensure continuing conformity; changes, modifications, and revisions related to production or service provision are controlled through the Document Change Notice (DCN) system. This system identifies, documents, and establishes the appropriate review and approvals for the changes.

Document Control is responsible for administering the DCN process, including review of changes, approval, implementation, distribution of DCNs, and maintaining the DCN records.

8.5.7 Release of Products and Services

At appropriate stages, planned arrangements are implemented to ensure product and service requirements have been met. The product release to the customer will proceed only after planned arrangements have been completed. Any deviation from this process will be approved by a relevant authority and if required by the customer. Documented information will be retained on the release of products and services that captures evidence of conformity with the acceptance criteria and release authorization traceability.

8.5.8 Control of Nonconforming Outputs

Products or Nonconforming Outputs that do not conform to stated requirements is identified and controlled to prevent its unintended use and delivery. The controls and related responsibilities and authorities for dealing with the non-conforming product is defined in Material Action Record Procedure.

Nonconforming product is any material/part/assembly/unit which does not conform to specification. Nonconforming product is promptly identified, documented and appropriately segregated. Manufacturing Engineering and or Quality Engineering has the responsibility to review Corrective Action Requests (CARs) and Preventive Action Requests (PARs) and disposition the referenced non-conforming parts.

Manufacturing and Quality Engineering reviews suspected or identified non-conforming product/output in accordance with approved and documented Procedures. Product identified as non-conforming may be:

- Reworked to meet the specified requirement;
- Accepted with or without repair, by concession;
- Re-graded for alternative applications;
- Rejected or scrapped.

9.0 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

Relia-Tek has planned and implemented the monitoring, measurement, analysis, evaluation and improvement processes needed:

- To demonstrate conformity of the product;
- To ensure conformity of the Quality Management System;
- To continually improve the effectiveness of the Quality Management System.

Relia-Tek applies suitable methods for monitoring and, where applicable, measurement of the QMS processes. These methods demonstrate the ability of the processes to achieve planned results.

Monitoring and measurement of the processes, as defined in 4.4 above, ensure that the process owners evaluate the performance and effectiveness of the Quality Management System itself.

When planned results are not achieved, corrective actions are taken, as appropriate, to ensure conformity of the product.

9.1.2 Customer Satisfaction

As one of the measurements of the performance of QMS, Relia-Tek monitors information relating to customer satisfaction. Customer satisfaction can be obtained from sources such as customer report cards, customer incoming quality data, or data from Returned Material Authorization (RMA).

Through regular customer satisfaction assessment, the corrective and preventive action tools will be used accordingly to address deficiencies and implement plans for customer satisfaction improvement.

9.1.3 Analysis and Evaluation

Relia-Tek collects and analyzes relevant data and information from monitoring and measurement to evaluate

- Customer satisfaction;
- Conformance to product requirements;
- Trends in process and product characteristics, including opportunities for preventive action and improvement;
- Performance of suppliers (external providers);
- Treatment effectiveness on risks and opportunities;
- Performance and effectiveness of QMS and its need for improvements.

9.2 Internal Audit

Internal audits verify that the Quality System conforms to the ISO 9001:2015 standard and to Relia-Tek's Quality Management System, and identify improvement opportunities.

The Quality Management structures and establishes the Relia-Tek audit program. The process owners for the area under audit are responsible for timely corrective action for any deficiencies or nonconformance found. Follow-up audit activities verify and record the effectiveness of the corrective action taken. The Quality Management is responsible for reviewing the internal audit program operation and effectiveness and making recommendations for improvement. Audit records are maintained as evidence of the implementation of the audit program and the audit results. Documented information such as Internal Audit Procedure describes this process in detail.

9.3 Management Review

On a regular basis, Top Management evaluates the Quality System's suitability, adequacy and effectiveness in satisfying the ISO 9001:2015 standard and the Relia-Tek Quality Policy contained in this manual.

The review includes assessment, decisions and actions related to opportunities for improvement, and the need for changes, resource needs to the management system. The review frequency, inputs, outputs, actions taken, required personnel and other review requirements are defined in the Quality Management Review Procedure. The output from management reviews of the QMS will be documented in records maintained by Quality Management.

10.0 Improvement

10.1 General

Relia-Tek determines and selects opportunities for improvement and implement any necessary actions aim to address the needs and expectations of customers as well as other interested parties. These typically include improving products and services; addressing future needs and expectations; eliminating, preventing or mitigating undesired effects and improving the performance and effectiveness of the QMS.

10.2 Nonconformity and Corrective Action

Corrective action is directed towards eliminating the causes of actual non-conformities and preventing recurrence.

The procedure for Corrective Action will define:

- the methods used to collect and review complaints and reports of product non-conformity,
- the requirements for, and methods used to determine the cause(s) of non-conformities (root cause analysis such as 5-Why, fishbone etc.).
- the requirements and responsibilities for evaluating when, and what, action is needed to ensure that the non-conformities do not recur,
- the requirements for and methods used to assign responsibility for implementing the actions,
- the requirements and responsibilities for verifying the implementation and the effectiveness of the corrective action, and
- the requirements and methods for recording the Corrective Action taken and the results of the verification.

In addition, preventive action is directed towards eliminating the causes of potential non-conformities. Preventive action involves using the appropriate information to detect, analyze, and eliminate potential causes of non-conformities and application of controls to ensure that the preventive action is effective.

10.3 Continual Improvement

Relia-Tek has established and implemented the systems and processes necessary to continually improve the suitability, adequacy and effectiveness of the Quality Management System (QMS). At least in part, facilitation of continual improvement shall be accomplished through the use of the quality policy, quality objectives, audit results, analysis of quality data, corrective and preventive action, and management review.

Appendix A – Operating Procedure Section Cross References

Operating Procedure (OP) / Work Instruction (WI)	Description	Section(s)
RT04-OP-01	Configuration Management	7.5, 8.0
RT04-OP-02	Control of Quality Records	7.1.5, 7.2, 7.5, 8.0, 9.2, 9.3, 10.0
RT04-OP-03	Quality Planning	6.0
RT05-OP-01	Management Review	9.3, 10.0
RT06-OP-01	Training and Awareness	7.2
RT07-OP-01	Contract Review	8.2, 8.4.2, 8.5.3
RT07-OP-02	Customer Feedback and Complaints	4.4, 8.2.1, 8.5.5
RT07-OP-03	Inspection, Measuring & Test Eqmt.	7.1.5, 8.5.3
RT07-OP-04	Process Control	8.5.1
RT07-OP-05	Design Control	8.3
RT07-OP-06	Supplier Assessment	8.4.1, 8.4.2
RT07-OP-07	Purchasing	8.4.3
RT07-OP-08	Receiving Inspection	8.4.2
RT07-OP-09	Set-up Inspection	8.5.1
RT07-OP-10	In-process Inspection	8.5.1
RT07-OP-11	Final Inspection	8.5.1
RT07-OP-12	Inspection and Test Status	7.1.5, 8.1, 8.5.1, 8.5.2
RT07-OP-13	Product Identification and Traceability	8.5.2, 8.5.7
RT07-OP-14	Product Handling	7.1.5, 8.5.4
RT07-OP-15	Storage and Preservation	7.1.5, 7.5.1, 8.5.4
RT07-OP-16	Packaging and Delivery	8.5.4
RT07-OP-17	Counterfeit Detection & Avoidance	8.4.2
RT08-OP-01	Customer Satisfaction	4.4, 9.1.2, 9.1.3
RT08-OP-02	Continual Improvement	4.4, 5.1.2, 5.2, 5.3, 6.1, 6.2, 7.2, 7.5.1, 9.0, 10.0
RT08-OP-03	Statistical & Analysis Techniques	6.1, 8.3.2, 9.1, 10.2, 10.3
RT08-OP-04	Control of Non-conforming Product	4.4, 8.5.8
RT08-OP-05	Internal Quality Audits	4.4, 9.2
RT08-OP-06	Corrective and Preventive Action	8.5.8, 9.1, 9.2, 10.0