



ISO 9001 Quality System Manual

Rotek Instrument Corp QUALITY MANUAL

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EXPLANATION OF LATEST REVISION

Per ECN QM900100-01-006:

Added ":1994" to ISO 9001 on pages 4,5 and 7 to emphasize that we are maintaining ISO 9001 to Rev 1994 and not to ISO 9000:2000.

Deleted reference to MISys on page 11.

Fixed misspelling of statistical on page 25.

REVISION STATUS OF PAGES

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ROTEK QUALITY POLICY

Rotek Instrument Corp. is dedicated to providing quality products and services in a constantly changing marketplace to meet the expectations and requirements of our new and existing customers.

ROTEK QUALITY OBJECTIVES

Develop and implement a quality system that complies with ISO 9001:1994.

Ensure that the direction of our quality effort focuses on fulfillment of our customer's needs with regards to our product safety, value, performance, reliability and usability.

Develop the culture of preventing defects instead of merely detecting them.

Involve all employees in the quality system in a continuous effort to improve our quality.

Monitor our overall quality performance to ensure that direction matches intent.

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INTRODUCTION

The purpose of this Quality Manual is to inform both our customers and our employees of Rotek's Quality System. The Quality System is based on the requirements of International Standard ISO 9001:1994.

SCOPE OF THE QUALITY SYSTEM

Rotek Instrument Corp. with facilities in Waltham, Massachusetts designs and manufactures voltage, current and power calibrators under the Quality System based on ISO 9001:1994.

DESCRIPTION OF COMPANY

Rotek Instrument Corp., organized in 1970, provides the link between users of electrical and electronic equipment and the fundamental electrical standards which are maintained by various governments. This linkage has taken the form of precise, working sources of voltage and current, which are used worldwide as the working standards of government and industry. These sources are commonly called "calibrators", and they are used primarily to test electrical meters.

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01 Management responsibility

QUALITY POLICY

Rotek's ISO 9001 Steering Committee is committed to the successful communication, implementation and maintenance of the company's Quality Policy.

ORGANIZATION

The authority and responsibility of all personnel affecting quality is defined by Rotek's Organization Chart. Verification activities are defined within the engineering, manufacturing and test processes. These programs are supported by trained personnel and adequate resources as determined by management. Internal quality audits are carried out by personnel independent of those having direct responsibility for the work being performed.

The Quality Assurance Manager is the management representative who is responsible for ensuring that the requirements of this quality system are implemented and maintained.

MANAGEMENT REVIEW

Annually, a review of the quality system determines the suitability and effectiveness of the system and identifies changes to the system if necessary.

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02 Quality System

Rotek has established and implemented a documented quality system in order to ensure that our products conform to specified requirements.

The quality system is documented by this Quality Manual, the Standard Operating Procedures (SOP's), work instructions, forms, operating instructions manuals and engineering documentation as necessary to meet the requirements of the ISO 9001:1994 Standard.

An ISO 9001 Family Tree which facilitates understanding of the entire system is provided. The ISO 9001 Family Tree, FT900100-01, references the quality-system procedures (SOP's) and outlines the structure of the documentation included in the quality system. The Quality Assurance Manager is directly responsible for the maintenance and the effective implementation of the quality system.

Quality plans are developed for new product to document how the requirements for quality will be met using our quality system.

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03 Contract review

Rotek reviews all customer purchase orders and contracts to ensure customer requirements are adequately defined and documented.

During the review, any differences between the customer's requirements and Rotek's capabilities are identified and communicated to the customer before release to manufacturing.

Changes to purchase orders are reviewed using the same procedure as with new purchase orders.

Records of all purchase orders are maintained by sales order entry personnel.

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04 Design control

When new product is designed at Rotek, design control procedures are followed to ensure that the product meets specified requirements.

The design and development is planned, responsibilities are defined, and qualified personnel and adequate resources are used. Organizational and technical interfaces are defined as well.

Design input is identified and documented in a "Product Specification". Design output in terms of engineering documentation is verified against design input.

Design reviews are held at appropriate stages of the design, design verification is performed to ensure that design-stage output meets design-stage input, and design validation is performed to ensure that product conforms to defined requirements.

Design changes are reviewed and approved by authorized personnel before implementation.

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05 Document and data control

At Rotek, all documents and data which relate to the quality system are controlled at introduction, as well as when they are changed.

The control consists of review and approval of documents by authorized personnel. The control ensures that the pertinent issues of documents are available at designated locations, and that obsolete documents are removed from these locations.

Changes to documents are reviewed and approved by the same functions that performed the original issue. Change information is included on the documents themselves or on the accompanying change order, where practicable.

To prevent use of non-applicable documents, the revision level of documents used in manufacturing current product is maintained in version control software (Source Safe). The revision level of documents used in manufacturing older product is controlled by reissue of the documents themselves.

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06 Purchasing

The purchasing of all material is performed at Rotek by the Purchasing department using our Manufacturing Inventory System, where appropriate. It is the responsibility of the Purchasing Manager to ensure that purchased product conforms to specified requirements.

Purchasing documents clearly and completely describe the product ordered. The buyer reviews and approves the purchasing documents prior to release.

When Rotek elects to verify purchased product at the subcontractor's premises, the arrangements and method of product release are specified on the purchase order.

Where specified in the contract, Rotek's customers are afforded the right to verify for themselves at Rotek or at our subcontractor's premises that purchased product conforms to specified requirements. Such product is still handled at Rotek using all standard operating procedures.

Rotek maintains a listing of all approved vendors. Vendors are approved based on their ability to meet all requirements. Procedures are in place to add new vendors to the list as well as to remove them from the list.

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07 Customer-supplied product

Material for products is generally supplied by Rotek. When a customer does supply product for incorporation into Rotek's instruments, such product is handled in the same manner as other product purchased for use in fulfilling the customer order.

Loss, damage or otherwise unsuitability of the customer supplied product will be recorded and reported to the customer.

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08 Product identification and traceability

Product is identified throughout the manufacturing and installation process by part number or model number. Subassemblies are identified by part number, and assemblies are identified by part number, serial number and/or model number.

Units which require customer traceability are identified by model number and serial number. This serial number serves as a key between the product configuration and the customer records for that unit.

Where traceability is a specified requirement, unique product and/or batch identification is recorded.

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09 Process control

At Rotek, the production and servicing processes are planned by our production control/customer service coordinator.

The production and servicing processes are carried out under controlled conditions, which include, when necessary, documented work instructions, use of suitable production equipment, a suitable work environment and compliance with standards, codes, quality plans and/or documented procedures. Monitoring and control points within the processes are defined. The approval of processes and process equipment is also defined where appropriate.

Workmanship criteria are defined in Rotek's written work instructions.

Special processes are those that cannot be fully verified by subsequent inspection and testing. We do not consider any of our processes to be special.

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10 Inspection and testing

RECEIVING INSPECTION AND TESTING

Rotek performs receiving inspection and test on product as identified on purchase orders to verify that it conforms to specifications. Material discrepancy reports are used as inputs for corrective action activities. In the event incoming product is released for urgent production purposes, it is identified and recorded.

IN-PROCESS INSPECTION AND TESTING

Rotek performs in-process inspection and testing on various subassemblies and units according to procedures or checklists. Defective product is either reworked to specification or replaced.

FINAL INSPECTION AND TESTING

Rotek performs final inspection and testing on all product to ensure that it meets specified requirements. No product is released until all activities have been satisfactorily completed and all data and documentation have been authorized.

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11 Control of inspection, measuring and test equipment

Inspection, measuring and test equipment are controlled, calibrated and maintained, when used at Rotek to demonstrate the conformance of our product to specified requirements. The equipment is used in a manner which minimizes the risk of unacceptable measurement error. The calibration system complies with the requirements of ANSI/NCSL Z540-1-1994.

Where test software or hardware are used as forms of inspection, they are included in the calibration system. Where specified, technical data pertaining to measuring equipment is made available to our customers.

Rotek's calibration procedures ensure that:

- . appropriate inspection, measuring and test equipment is selected
- . such equipment is calibrated at prescribe intervals
- . equipment is calibrated against nationally recognized standards
- . calibration procedures control the process
- . calibration stickers indicate calibration status
- . calibration records are maintained
- . out of calibration test results are assessed
- . environmental conditions are suitable
- . equipment is handled, preserved and stored properly
- . calibration seals safeguard adjustments

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12 Inspection and test status

Product inspection and test status is identified throughout the production process to ensure that only product that has passed the required inspections and tests is used or shipped. The inspection authority responsible for the release of conforming product is identified.

The inspection and test status is identified by using physical location, operator stamps, tags, labels, test data, reports, certificates and packing lists as appropriate.

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13 Control of nonconforming product

Nonconforming product is identified, documented, evaluated, segregated, when practical, and disposed of in accordance with documented procedures at Rotek. The procedures ensure that nonconforming product is not inadvertently used, and that reworked product is re-inspected and tested.

NONCONFORMITY REVIEW AND DISPOSITION

Responsibility for review and disposition of nonconforming product is identified. Product is reviewed to determine if it can be reworked to meet specifications, accepted by concession, regraded, or rejected or scrapped. Material discrepancy reports, inspection and material reports, and reject tags are used to record the process.

Where required by contract, the customer is contacted for acceptance by concession of a nonconforming product, and the facts are recorded in the customer's sales file.

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14 Corrective and preventive action

Corrective and preventive action processes are key for the success of Rotek's continuous improvement goals. Corrective actions are initiated as a result of problem identification by any Rotek employee, or as a result of customer complaints, warranty repairs, process problems and /or supplier nonconformities.

Personnel responsible for the corrective and preventive action are identified and action teams are assigned to ensure that the problem is analyzed, root causes are determined, corrective and preventative actions are initiated, and they are implemented and effective.

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15 Handling, storage, packaging, preservation and delivery

At Rotek, product is handled throughout receiving, storing, manufacturing and shipping in such a way as to protect it from harm.

Special handling is provided for ESD sensitive product to protect it from damage.

Procedures are in place for receiving and storing product prior to release to manufacturing. Product is stored in designated storage areas, access to product is controlled, inventory accuracy is monitored by the Rotek MISys, manufacturing inventory system, and the condition of the stored product is assessed at periodic intervals. FIFO (First In, First Out) techniques are used to minimize deterioration of product while in storage.

Shipping materials are designed so that trained personnel can pack and ship Rotek product to our customers without damage to the product.

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16 Control of Quality Records

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

Quality records and the manager responsible for their maintenance are identified. Quality records are normally maintained in the department responsible for their establishment so that they are readily available.

Quality records are maintained for a minimum of seven years, unless specified otherwise by contract or procedure.

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17 Internal quality audits

Internal quality audits are performed at Rotek to determine the effectiveness of our quality system and to verify that quality activities and results comply with our plans.

The audits are planned and scheduled based on the importance of the activity. Trained personnel carry out the audits according to documented procedures which specify the audit, discrepancy reporting, timely corrective action and follow-up. The internal auditors are independent of the areas being audited.

Internal quality audit records are filed by quality assurance, and they are used as a basis for the annual review of the quality system by Rotek's ISO 9001 Steering Committee.

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18 Training

Training is provide at Rotek to strengthen our employees capabilities and to raise their understanding and level of involvement in our quality system.

The training needs of all employees are assessed on an annual basis, as a minimum.

Personnel are selected to perform assigned tasks based on education, previous training and/or experience, and they receive additional job training as required. Retraining is provided to individuals whose job performance indicates such action is needed.

All employees are trained in the ISO 9001 Quality System and safety, and specialized skills training is provided to those individuals involved in certain identified processes.

Training records are maintained by the Human Resources Manager in the employee training file.

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19 Servicing

Repair and calibration services are provided at the factory for all Rotek products. Service contracts, which include factory repairs and two scheduled calibrations per year, are available for newly purchased units.

When service is performed, equipment will be repaired and calibrated to meet all specifications, unless otherwise specified. Rotek will provide spare part replacement and product support for a minimum of five years from the date of product discontinuance.

Servicing records including warranty repair data and customer complaint data are used as inputs to our corrective action system to make sure continuous improvement is being achieved.

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20 STATISTICAL TECHNIQUES

Rotek has established a procedure for identifying the need for statistical techniques.

Where appropriate, Rotek will develop work instructions for statistical techniques to verify the acceptability of process capability and product characteristics.

Engineering is available to assist in the proper use of statistical techniques.