



**Ralston Instrument LLC Quality Manual**  
**Revision 8 (Printed copies are not controlled)**

TABLE OF CONTENTS

- 4 Quality Management System
  - 4.1. General Requirements
  - 4.2. Documentation Requirements
    - 4.2.1. General Requirements
    - 4.2.2. Quality Manual
    - 4.2.3. Control of Documents
    - 4.2.4. Control of Records
- 5 Management Responsibility
  - 5.1. Management Commitment
  - 5.2. Customer Focus
  - 5.3. Quality Policy
  - 5.4. Planning
    - 5.4.1. Quality Objectives
    - 5.4.2. Quality Management System Planning
  - 5.5. Responsibility | Authority and Communication
    - 5.5.1. Responsibility and Authority
    - 5.5.2. Management Representative
    - 5.5.3. Internal Communication
  - 5.6. Management Review
    - 5.6.1. General
    - 5.6.2. Review Input
    - 5.6.3. Review Output
- 6 Resource Management
  - 6.1. Provision of Resources
  - 6.2. Human Resources
    - 6.2.1. General
    - 6.2.2. Competence, Awareness and Training
  - 6.3. Infrastructure
  - 6.4. Work Environment
- 7 Product Realization
  - 7.1. Planning of Product Realization
  - 7.2. Customer-Related Processes
    - 7.2.1. Determination of Requirements Related to the Product
    - 7.2.2. Review of Requirements Related to the Product
    - 7.2.3. Customer Communication
  - 7.3. Design and Development
  - 7.4. Purchasing
    - 7.4.1. Purchasing Process
    - 7.4.2. Purchasing Information
    - 7.4.3. Verification of Purchased Product
  - 7.5. Production and Product Provision
    - 7.5.1. Control of Production
    - 7.5.2. Validation of Processes for Products Provision
    - 7.5.3. Identification and Traceability
    - 7.5.4. Customer Property
    - 7.5.5. Preservation of Product
  - 7.6. Control of Monitoring and Measuring Devices
- 8 Measurement, Analysis and Improvement
  - 8.1. General
  - 8.2. Monitoring and Measurement



## 4 Quality Management System

### 4.1. General Requirements

Ralston Instruments LLC's business is the manufacture of pressure calibration products, hoses, adaptors and gas calibration sources. Ralston Instruments designs the majority of parts, has them manufactured by third parties and performs assembly and testing of the products.

This Quality Manual outlines Ralston Instruments LLC Quality Management System. The processes referenced define the Quality Management System implemented to ensure that Ralston Instruments LLC consistently provides and continually improves a product that conforms to its' customers' requirements. Ralston Instruments LLC quality system was established in accordance with the requirements of ISO 9001 :2000 standards. When applicable documented customer requests supersede internal Quality Management System procedures.

Through the establishment of this Quality Management System, Ralston Instruments LLC identified the required quality process and their application and the Process Interaction Map documents the interaction throughout the organization. The process for ensuring the continuing suitability and effectiveness of the Quality Management System is defined in Procedure 5.6: Management Review. The assessment of availability of resources and information necessary to support the Quality Management System is evaluated through Procedure 6.2: Human Resources. The design and development of products is controlled through Procedure 7.3: Design and Development. The monitoring, measurement and analysis of the quality processes are established through Procedure 8.2: Monitoring and Measurement. Procedure 8.5: Improvement implements the process used to continually improve the processes within Quality Management System.

### 4.2. Documentation Requirements

#### 4.2.1. General Requirements

Ralston Instruments' Quality Management System documentation includes:

- Quality Policy
- Quality Objectives
- *Quality Manual*
- Documented Procedures, Work Instructions and Forms are listed In the Master Record Control List.
- Ralston Instruments uses these documents to ensure the effective planning operation and control of the Quality Management System and the ISO 9001:2000 standards
- Quality records are generated as required through the use of Quality Management System documents

Ralston Instruments LLC Quality Management System documents are maintained in electronic form and available where operations take place.

The following are definitions and terms used within the Quality Management System documentation:

- Ralston Instruments: Ralston Instruments LLC.
- First Tier Supplier: Direct supplier who makes part per our specifications
- Second Tier Supplier: Supplier who makes standard parts that are used in our products



#### 4.2.2. Quality Manual

The purpose of this *Quality Manual* is to outline the Quality Management System of Ralston Instruments and identify the documented procedures established to implement this system. The Process Interaction Map provides a description of the interaction between the processes of the Quality Management System.

The following are notable interpretations of the ISO 9001 :2000 procedures as they apply to the design of Ralston Instruments Quality Management System:

#### 4.2.3. Control of Documents

Current issues of appropriate documents are available at Ralston Instruments operations. All approvals and changes to documentation are recorded according to Procedure 4.2: Documentation Requirements. Master Record Control List identifies all controlled documents. The Management Representative or designate is ultimately responsible for changes, approval and distribution of quality documents. The detailed process for document control is defined in Procedure 4.2 Documentation Requirements.

Obsolete documents, paper and electronic, shall be promptly removed from all areas of use. Quality documents are required to remain legible and readily identifiable.

#### 4.2.4. Control of Records

The Management Representative or designate is responsible for implementation and maintenance of Quality Management System requirements for record control. All records that relate to the Quality Management System and conformance to standard requirements will be listed on the Master Record Control List. The records must be properly labeled, legible and organized. The records must be maintained to prevent damage and be readily accessible to whoever may need them.

Records will be maintained for the retention time period defined on the Master Record Control List. Retention times of records will be in accordance with legal and contractual requirements when applicable. The detailed process for control of records is defined in Procedure 4.2: Documentation Requirements.

## 5 Management Responsibility

### 5.1. Management Commitment

Ralston Instruments Management demonstrates it is committed to the development and implementation of the Quality Management System and continually improving its effectiveness through:

Communicating to the organization the customer, statutory and regulatory requirements Communicating to the organization the Quality Policy

- Communicating to the organization the Quality Objectives
- Conducting Management Reviews
- Ensuring the availability of resources to implement the Quality Management System
- The detailed process and control of Management Commitment is defined in Procedure 56: Management Review.

### 5.2. Customer Focus

This quality system aims to enhance customer satisfaction through the effective application of the Quality Management System, including processes for continual improvement of the system and the assurance of conformity to customer requirements.

The incorporation, documentation, communication and measurement of customer requirements are defined in Procedure 72: Customer-Related Processes.



### 5.3. Quality Policy

Management developed the Quality Policy to reflect the scope and purpose of the organization. The Quality Policy is communicated to and understood by employees throughout the organization. The Senior Management Team reviews the Quality Policy for continued suitability according to Procedure 5.6: Management Review.

### 5.4. Planning

#### 5.4.1. Quality Objectives

Ralston Instruments Management Team develops and applies Quality Objectives, with input from the customer, local management and transportation partners. These objectives are consistent with Ralston Instruments Quality Policy and customer requirements. The objectives shall be communicated, applied and measured according to Procedure 8.4: Analysis of Data.

#### 5.4.2. Quality Management System Planning

Quality planning is initiated at Management Review meetings. Overall planning requirements are determined and implemented by the Senior Management Team.

The Quality Management System is defined and controlled through the quality documents and procedures identified in the *Quality Manual*. The Quality Management System procedures, work instructions and forms meet the requirements as outlined in the *Quality Manual*. The effectiveness of the Quality Management System is evaluated through Procedure 56: Management Review and is continually improved as identified.

### 5.5. Responsibility, Authority and Communication

#### 5.5.1. Responsibility and Authority

The Management Team, through Procedure 5.6: Management Review, shall ensure that the procedures are consistently applied to all work and that they are updated regularly to reflect current customer requirements.

The departmental managers and departmental personnel shall implement procedures and integrate requirements into their regular duties. Assurance of quality and improvement involves everyone in the organization. All personnel in their daily work activities shall practice quality assurance by working in a formalized, systematic manner designed to eliminate errors (defects) and nonconforming Products.

The Management Representative or designate shall monitor the implementation of the Quality Management System and carry out verification activities to ensure the system is effective. The Management Representative or designate shall ensure that independent internal audits are conducted to monitor the compliance and effectiveness of the procedures that pertain to the quality system.

The Management Representative or a designate will represent Ralston Instruments on all matters relating to quality.

#### 5.5.2. Management Representative

A Management Representative has been appointed with authority and responsibility for ensuring that the Quality Management System described in this manual meets the requirements of ANSI/ISO/ASQ Q9001 2000 and is implemented and maintained.

The Management Representative will report performance to management for review and improvement of the Quality Management System.

Ralston Instruments Management Team appointed the Operations Manager as the Management



Representative.

See attached Organizational Chart.

#### 5.5.3. Internal Communication

The organization shall ensure that communication processes to discuss the effectiveness of the Quality Management System will be established and followed according to Procedure 5.6: Management Review.

### 5.6. Management Review

#### 5.6.1. General

The Senior Management Team shall conduct reviews of the Quality Management System to ensure continuing suitability and effectiveness. The reviews will be conducted as defined in Procedure 5.6: Management Review. The reviews should include evaluation of internal audit results and follow-up corrective and preventive action, customer concerns, nonconforming Product and product reports and the continual suitability of the Quality Policy.

#### 5.6.2. Review Input

The review input for the Management Review is defined in Procedure 56 Management Review.

#### 5.6.3. Review Output

The review output for the Management Review is defined in Procedure 5.6: Management Review.

## 6 Resource Management

### 6. 1. Provision of Resources

The organization's responsibility to provide adequate resources, personnel, training and leadership to execute the Quality Policy and the entire Quality Management System is defined in Procedure 6.2: Human Resources.

### 6.2. Human Resources

#### 6.2.1. General

Personnel performing work affecting the performance of customer requirements shall be competent on the basis of appropriate education, training, skills and experience as defined in Procedure 6.2: Human Resources.

#### 6.2.2. Competence, Awareness and Training

Ralston Instruments shall identify training needs and ensure training is provided for processes affecting quality. Individuals who require specialized skills will be trained. Records of training and certification will be maintained to verify that individuals have been given the appropriate training to meet the needs of their assigned tasks. The detailed process for competence, awareness and training is defined in Procedure 6.2: Human Resources.

### 6.3. Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to customer requirements as defined in Procedure 6.2: Human Resources. The infrastructure shall include workspaces, hardware and software equipment and supporting communication Products.

### 6.4. Work Environment



The organization shall determine and manage the work environment needed to achieve conformity to customer requirements as defined in [Procedure 6.2 Human Resources](#).

## 7 Product Realization

### 7.1. Planning of Product Realization

The organization shall plan and develop processes needed for product realization. Planning will be consistent with other processes in the quality management system. These processes are defined in the quality plan [Procedure 7.1 Planning of Product Realization](#).

### 7.2. Customer-Related Processes

#### 7.2.1. Determination of Requirements Related to the Product

All customer contracts and purchase orders will be reviewed prior to commencement of manufacture to ensure that Ralston Instruments can meet customer requirements and expectations as defined in the proposed business offering. Records will be maintained of these reviews.

Discrepancies between the customer and Ralston Instruments will be reviewed and recommendations made to the customer for resolution. Methods for making changes to orders and communicating changes within Ralston Instruments will be defined. The detailed process for evaluating and communicating customer requirements is defined in [Procedure 7.2: Customer-Related Processes](#). These documents shall reflect the requirements of the ISO 9001:2000 standard and Ralston Instruments' [Quality Policy](#).

#### 7.2.2. Review of Requirements Related to the Product

Ralston Instruments shall review the customer requirements for Product according to [Procedure 7.2: Customer-Related Processes](#).

#### 7.2.3. Customer Communication

Ralston Instruments shall communicate with the customer regarding Product requirements, contracts and contract amendments, customer feedback as defined in [Procedure 7.2: Customer-Related Processes](#).

### 7.3. Design and Development

#### 7.3.1 Design and development planning

Ralston Instruments shall plan and control the design and development of its products. Ralston Instruments shall determine the design and development stages of products, the review, verification and validation that are appropriate to each design stage. Ralston Instruments should determine the responsibilities and authorities for design and development of products as defined in [Procedure 7.3: Design-Related Processes](#). Ralston Instruments shall manage the interfaces involved in design and development to ensure effective communication and clear understanding by all parties.

#### 7.3.2 Design and development Inputs

Inputs related to the product requirements shall be determined and maintained. The inputs will include functional and performance requirements, applicable statutory and regulatory requirements and other necessary requirements associated with design as defined in [Procedure 7.3: Design-Related Processes](#). These inputs shall be reviewed by the Engineering department to ensure their accuracy.

#### 7.3.3 Design and Development outputs

The outputs of design and development shall be provided in a form that enables verification against the



design and development input and shall be approved by the Engineering Department prior to release. The design and development outputs shall meet the requirements for design and development, provide appropriate information for purchasing, production, and for service provision, contain or reference product acceptance criteria, and specify the characteristics of the product that are essential for its safe and proper use as set forth in Procedure 7.3 Design-Related Processes.

#### 7.3.4 Design and Development review

At suitable stages in the design process, systematic reviews of the design and development shall be performed in accordance with arrangements made in Procedure 7.3: Design-Related Processes. These reviews will be made to evaluate the ability of the results for design and development to meet the design requirements and to identify any problems and propose the necessary actions. The participants of the review will be the leader functions concerned with the design and development stages to be reviewed. Records shall be maintained.

#### 7.3.5 Design and development verification

Verification shall be performed in accordance with arrangements in 7.3.1 Design and development planning to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification shall be maintained in accordance with Procedure 4.2.4: Control of Records.

#### 7.3.6 Design and development validation

Design and development validation shall be performed in accordance with the planned arrangements made in 7.3.1 Design and development planning. This ensures that the resulting product is capable of meeting the requirements for the specified application or intended use. Validation shall take place prior to the delivery of the product.

#### 7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated as appropriate and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent products already delivered. Records of the review shall be maintained in accordance with 4.2.4 Control of Records.

## 7.4. Purchasing

Ralston Instruments purchased both standard parts as well as parts that were specifically manufactured for Ralston Instruments. Ralston Instruments additionally resells certain products. All First Tier and Second Tier suppliers are qualified and approved prior to use for their ability to provide Products as required by Ralston Instruments.

#### 7.4.1. Purchasing Process

The contracted suppliers' controlled products will be determined by the Management Representative or designate with input from the Engineering Department. The final list of controlled products will be recorded in Ralston Instruments' Purchasing Products Control List. The process for internal supplier purchasing is detailed in Procedure 7.4: Purchasing.

#### 7.4.2. Purchasing Information

The Management Representative or designate shall ensure that all supplier requirements are communicated through the Purchasing Products Control List as defined in Procedure 7.4: Purchasing.

#### 7.4.3. Verification of Purchased Product

Ralston Instruments First tier suppliers' performance is periodically assessed and evaluated. Suppliers will



be measured according to Procedure 8.4: Analysis of Data.

If specified in a contract, Ralston Instruments customers may verify that incoming Ralston Instruments products conform and/or meet specified requirements. However, such Ralston Instruments customer verification shall not be used by Ralston Instruments as evidence of supplier quality controls nor absolve Ralston Instruments of providing acceptable products to the customer.

## **7.5. Production and Product Provision**

### **7.5.1. Control of Production**

Ralston Instruments' production shall be defined and planned. The production process shall be carried out under controlled conditions, with documented instructions, in compliance with standards / codes, established workmanship criteria and approved processes. The detailed process for the control of Product is defined in Procedure 7.5: Production.

### **7.5.2. Validation of Processes for Products Provision**

The status of the Product completed at each phase of production will be recorded to show completion of the Product to specified requirements. The detailed process to identify the status of Product is defined in Procedure 7.5: Production.

The Product processes shall be monitored and controlled continuously through Procedure 8.4: Analysis of Data.

### **7.5.3. Identification and Traceability**

Ralston Instruments shall identify and trace materials through all phases of receipt, manufacturing, processing, storage and delivery where applicable. The Quality Assurance Manager is responsible for assigning and controlling material throughout the process, accurately labeling information where applicable and maintaining documentation. All material will be controlled to assure identity to part number, material type, supplier and order number where applicable.

Where traceability is a requirement Ralston Instruments shall serialize individual finished products to aid in traceability. Otherwise lots of material are tracked.

### **7.5.4. Customer Supplied Material**

Material and product classified as Customer-Supplied product by Ralston Instruments is defined and controlled to provide positive identification. The use of Customer-Supplied product is limited to unique circumstances and is handled as a special requirement.

### **7.5.5. Preservation of Product**

Ralston Instruments shall preserve the conformity of the product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the parts which constitute the finished goods.

## **7.6. Control of Monitoring and Measuring Devices**

Ralston Instruments will maintain inspection and test equipment used to demonstrate conformance to



specified requirements. Test equipment is controlled, calibrated and maintained to provide confidence in decisions or actions resulting from the measurement data.

The Quality Assurance Manager is responsible for establishing calibration requirements used to control inspection. Subcontractors used for calibration or testing are held to international standards and must maintain certification with an internationally recognized certifying body. Serial numbers and other labeling techniques are used to ensure traceability to an international standard organization.

## 8. Measurement, Analysis and Improvement

### 8.1. General

Ralston Instruments shall define the processes needed to demonstrate product conformity and ensure conformity and improvement of the Quality Management System as defined in Procedure 8.4: Analysis Data

### 8.2. Monitoring and Measurement

#### 8.2.1. Customer Satisfaction

The organization shall monitor customer satisfaction relating to achievement of customer requirements as defined in Procedure 8.4: Analysis of Data.

#### 8.2.2. Internal Audit

Ralston Instruments shall plan, schedule and conduct internal operational audits. The audit results and corrective action(s) taken on findings will be incorporated into Procedure 5.6 Management Review.

All internal audits, initial or follow-up, shall be scheduled on the basis of status and importance, conducted by personnel independent of the activity, and results recorded and brought to the attention of the responsible party. The detailed process for internal audits is defined in Procedure 8.2: Monitoring and Measurement.

#### 8.2.3. Monitoring and Measurement of Processes

The organization shall monitor and measure its Quality Management System procedures as defined in Procedure 8.2 Monitoring and Measurement. Processes and process equipment are qualified and validated to ensure the ability to meet specified requirements identified during quality planning. Process control may include statistical analysis, in-process inspection, final inspection or test and Bill of Materials (BOM). Manufacturing and assembly processes are monitored and controlled in accordance with quality plans to ensure specified requirements are met.

#### 8.2.4. Monitoring and Measurement of Product

The organization shall monitor and measure its Product performance as defined in Procedure 8.4: Analysis of Data. Products are monitored and measured to ensure quality throughout the manufacturing process. Evidence of conformity with the acceptance criteria shall be maintained. All pressure related products shall maintain a 4:1 factor of safety unless noted. Testing intervals shall be determined using statistical process control. Products shall be monitored using a statistical process control system. Records shall indicate the person authorizing release of product in accordance with 4.2.4: Control of Records.

### 8.3. Control of Nonconforming Product

Ralston Instruments shall identify and control Products that do not conform to established requirements. Any affected product will be identified by serial number (where applicable) to prevent inadvertent use. Nonconforming incoming product(s) shall be reviewed and formal disposition identified. Any repaired



nonconforming incoming product(s) shall be re-inspected prior to release. The detailed process to prevent nonconforming product(s) from inadvertent use is defined in Procedure 8.3: Control of Nonconforming Product.

## 8.4. Analysis of Data

Ralston Instruments shall promote the use of data analysis in appropriate for the use of quality system measurement. Measurements will be used to reduce variation and improve confidence in Product and performance. The detailed process for analysis of data is defined in Procedure 8.4: Analysis of Data.

## 8.5. Improvement

### 8.5.1 Continual Improvement

Ralston Instruments shall continually improve the effectiveness of the quality management system through the use of the Quality Policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

### 8.5.2 Corrective Action

Any employee, contractor or vendor within the Ralston Instruments organization can initiate a corrective action where actual or potential nonconformities are identified. These areas include but are not limited to inspection activities, quality investigations, supplier audits or internal quality audits. The required due date is assigned based on the significance of the nonconformity identified and the potential impact on such aspects as performance and customer satisfaction.

A notification is completed and issued to the responsible manager, supervisor or supplier using a format indicating an identification number, statement of problem, date issued, reply due date and response information. Responses to a corrective action are performed using the standard form which includes the following: Identification of the root cause of the deficiency, short or long term action to prevent recurrence and the planned implementation date. Responses to corrective actions are evaluated to ensure that the issue has been properly addressed and resolved and there will not be a future recurrence.

### 8.5.3 Preventative Action

Ralston Instruments will initiated by monitoring key performance indicator trends. Analysis of data will provide data that will help to take preventative action.