

# **G&R Labs Quality Manuel**

## TABLE OF CONTENTS

		page
<b>1.0</b>	Scope.....	3
<b>2.0</b>	References.....	3
<b>3.0</b>	Definitions.....	3
<b>4.0</b>	Quality-System Requirements.....	3
<b>4.1</b>	Management Responsibility.....	3
<b>4.2</b>	Quality System.....	4
<b>4.3</b>	Contract Review.....	5
<b>4.4</b>	Design Control.....	5
<b>4.5</b>	Document and Data Control.....	5
<b>4.6</b>	Purchasing.....	6
<b>4.7</b>	Control of Customer-Supplied Product.....	6
<b>4.8</b>	Product Identification and Traceability.....	7
<b>4.9</b>	Process Control.....	7
<b>4.10</b>	Inspection and Testing.....	7
<b>4.11</b>	Control of Inspection, Measuring and Test Equipment.....	8
<b>4.12</b>	Inspection and Test Status.....	9
<b>4.13</b>	Control of Nonconforming Product.....	9
<b>4.14</b>	Corrective and Preventive Action.....	9
<b>4.15</b>	Handling, Storage, Packaging, Preservation and Delivery.....	9
<b>4.16</b>	Control of Calibration Records.....	9
<b>4.17</b>	Training.....	10
<b>4.18</b>	Servicing.....	10
<b>4.19</b>	Statistical Techniques.....	10

## 1.0 SCOPE

This Quality Manual outlines the policies, procedures and requirements of G&R Labs Quality System. G&R Labs Quality System is structured to comply with the conditions set forth in the International Standard ISO 9002:1994 (ISO 9002) and ANSI/NCSL Z540-1-1994 (Z540-1).

## 2.0 REFERENCES

2.1 International Standard ISO 8402:1994, Quality Management and Quality Assurance - Vocabulary.

2.2 International Standard ISO 9002:1994, Quality Systems - Model for Quality Assurance in Production, Installation and Servicing.

2.3 ISO 17025-1:1993-03-15, Quality Assurance Requirements for Measuring Equipment – Part 1.

2.4 ANSI/NCSL Z540-1-1994, Calibration Laboratories and Measuring and Test Equipment - General Requirements.

## 3.0 DEFINITIONS

3.1 This section is for definitions not referenced in ISO 8402.

3.1.1 Customer-owned property - Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.

3.1.2 Customer-supplied product - Any type of service material supplied to G&R Labs to be utilized in modification or repair of or used with customer-owned property.

3.1.3 Distribution Material - Distribution material is product which is G&R Labs (company) owned and is used for resale.

3.1.4 Local Service Procedures - These are procedures written by G&R Labs for calibration and repair on instrumentation which do not have written manufacture procedures or for clarification on existing written procedures.

1. Service Material - Service material is product (parts, components, assemblies, etc.) that is used to repair or modify distribution material or customer-owned property.

## 4.0 QUALITY-SYSTEM REQUIREMENTS

### 4.1 Management Responsibility

#### 4.1.1 Quality Policy

G&R Labs Quality Policy is for management to provide the training and leadership to all employees in the art of continuous improvement and to constantly seek improved quality at reduced costs that still exceed the expectations of our customers and/or industry standards.

This policy will be evaluated at least once a year by management to confirm the suitability and effectiveness of this policy is being met. It is management's responsibility to ensure this policy is understood, implemented and maintained by all personnel of the organization.

#### 4.1.2 Organization

##### 4.1.2.1 Responsibility and authority

Personnel listed below have the responsibility and authority to manage and verify the work affecting quality. They have the freedom and authority to initiate action to prevent the occurrence of any nonconformity relating to the product, process and quality system; they have the responsibility to identify and record any problems relating to the quality process, initiate solutions and verify the implementation of these solutions. The President is responsible for the organizational structure, allocation of resources and the development of policies to ensure the implementation of G&R Labs quality system and its conformance to ISO 9002:1994 and ANSI/NCSL Z540-1-1994 requirements. The President is also responsible for developing, directing and monitoring the quality system's goals, procedures and policies. The QA Manager is responsible for the coordination of all quality activities of G&R Labs organization. The QA Manager is the President.

##### 1. Resources

The President identifies resource requirements and provides adequate resources, including the assignment of trained personnel for the management, performance of work and verification activities including internal quality audits.

#### 4.1.2.3 Management Representative

The President is designated as Management Representative with defined authority for:

- a) Ensuring that a quality system is established, implemented and maintained in accordance with ISO 9002 and ANSI/NCSL Z540-1 and
- b) Getting feedback on the performance of the quality system from the calibration technician, to review and look for improvement of the quality system.

#### 4.1.3 Management Review

Management will make periodic reviews at all operational levels to assess the quality system's continuing suitability and effectiveness in meeting the requirements of ISO 9002 and Z540-1. These reviews will be held on a quarterly basis or at closer intervals when necessitated.

#### References:

FQD 100 - Management Review

## 4.2 Quality System

### 4.2.1 General

G&R Labs shall establish, document and maintain a Quality System to ensure a quality program that supports its effort to provide customers with quality products and services. G&R Labs quality system consist of two main areas:

#### 4.2.1.1 Sales

To provide efficient sales service to meet the needs of the customer's requirements, stated or implied.

#### 4.2.1.2 Service

To provide expedient repair and calibration services, which meet customer's requirements and/or the industry standards.

### 4.2.2 Quality System Procedures

Calibration procedures are documented to establish and maintain continuity of each Calibration quality. Calibration procedures will be readily available to personal for reference and implementation. The calibration document structure is illustrated Below.

1. Master Calibration Procedure
2. OC99 Calibration Procedure  
From Master Standard to Secondary Standard
3. OC100 Calibration Procedure  
From Secondary Standard to Probe being Calibrated
4. OC101 Calibration of Intensity Meters  
Meters 100, 150, 200, 202 & Similar Models
5. OC102 Calibration of Model 320
6. OC103 Calibration of Model 400
7. Master Certificate of Calibration for the Digital Pyroelectric Radiometer Probe  
Reflectance Data on Black Thermopile Surface

### 4.2.3 Quality Planning

The requirements for quality will be met by documenting specific measurement practices and activities for all instruments, understanding and meeting customer needs and with emphasis on problem prevention. Changes to the calibration procedure will be made as conditions or services change or mature. All changes will be consistent with all other requirements of the company's quality management system. Calibration procedure planning should include:

1. The preparation of the procedures.

2. Acquiring appropriate Measurement and Test Equipment, processes, fixtures, resources and skills that may be needed to achieve the required quality results;
3. Making sure that the test procedures and documentation are appropriate;
4. Changing test procedures as required;
5. Identification of necessary measurement requirements, test equipment and required traceability;
6. Identification of triggers that require customer interface
7. Ensuring that appropriate standards are met to assure required product performance;
8. Preparation of test procedures and calibration certificates.

References:

FQD 180 - Servicing; FPD 370 - Calibration

#### 4.3 Review

##### 4.3.1 General

Procedures shall be established and maintained for procedure review. The President is responsible for coordinating and supervising procedure review to make sure that the needs of the customer are well understood and documented, and that all requirements can be met. Customer/company interface is maintained mainly by the president or people assigned to a particular customer interface.

##### 4.3.2 Reviewing

###### 4.3.2.1 Sales

Customer contracts and purchase orders are reviewed to ensure that all stated requirements are understood and can be adhered to. Options, such as product modification will be reviewed for compliance to the customer requirements. Any discrepancy or deviation in previously agreed terms for payment, delivery and/or technical requirements must be remedied prior to acceptance.

###### 4.3.2.2 Service

Customer orders are reviewed to ensure that all the stated requirements are understood and can be adhered to. Any deviation in terms for payment, delivery and/or technical specifications must be remedied prior to acceptance.

##### 4.3.3 Amendments

Amendments to any order or contract may be submitted in writing or negotiated by telephone, FAX or E-mail. If negotiated by telephone, a written record will be made and placed with the original purchase order or contract. All changes must be reviewed and approved by designated personal prior to implementation. Ultimate responsibility is the President's.

##### 4.3.4 Records

Customer purchase orders will be maintained while active and archived as stated in section 4.16.

References: FQD 130 - Contract Review

#### 4.4 Design Control

The scope of this International Standard does not include quality-system requirements for design control. This subclause is included to align the clause numbering with ISO 9000.

#### 4.5 Document and Data Controls

##### 1. Internal Documents

###### 1. General

G&R Labs will establish and maintain a documented procedure to control all documents and data that relate to the requirements of ISO 9002 and Z540-1. Internal documents are controlled with current revisions identified in the Master Document Index. This index is maintained by the President.

###### 1. Document and data approval, issue, and control authority

All new or revised internal documents shall be approved by the President. He will oversee tracking the status, revision number, and location of all documentation under his control. The President will ensure that appropriate documents are available at all locations

where operations essential to the effective functioning of the quality system are performed; that invalid and/or obsolete documents are promptly removed from all points of issue or use and obsolete documents, if retained for legal and/or knowledge- preservation purposes, are suitably identified. The central (control ) authority for all documentation is the President.

The President will ensure that:

All documents are up to date, available where needed, signed and dated with revision numbers, and reissued when appropriate and that obsolete documents are replaced; changes to documents and data shall be reviewed and approved. All documents need to be reviewed at least once per year.

This policy meets the requirements of Section 4.5 of ISO 9002 and Section 5.0 of ANSI/NCSL Z540-1-1994.

1. External documents

1. Sales Department (Documents of External Origin are not controlled)

1. Service

Documents of External Origin that apply to calibration, test, modification, upgrade, service and repair of all Measurement and Test Equipment are indexed and placed in the calibration information binder. Changes to these documents supplied by the Original Equipment Manufacturer are incorporated. Changes made to these documents will be noted on the document in an appropriate location.

Documents that do not pertain to the calibration and/or service process ( sales literature, technical information of general purpose, sketches and notes made to assist in departmental work, technical magazines, and literature and manuals of uncontrolled equipment such as computers and other 'tools' are uncontrolled.

#### References:

FQD 110 - Document Control

FQD 111 - Data Control

FPD 121 - Internal Audits

## 4.6 Purchasing

### 4.6.1 General

G&R Labs will replace batteries in customer equipment but will not usually do any repair. G&R Labs will repair and upgrade their own meters when necessary.

#### References:

FQD 160 - Purchasing; FPD 370 Calibration System

## 4.7 Control of Customer-Supplied Product

The calibration technician is responsible for the control of customer supplied products while they are at G&R Labs.

When customer-supplied product is received it is inspected for correct quantity, proper identification and possible shipping damage. Accompanying paper work is checked for clearness of instructions. The material is then placed in a unique area for identification. Care is taken to preclude physical damage while at G&R Labs by the unique storage area. Material to be calibrated/verified or repaired is noted. Procedures for control of customer supplied material are referenced below.

(Reference: FQD 150 - Warehousing; FQD 140 - Material Identification and Traceability; FPD 370 - Calibration System )

## 4.8 Product Identification and Traceability

The calibration technician is responsible for product identification and traceability of product at all stages of calibration and delivery. All customer owned material is recorded at receipt. All material is then stored in unique locations for both protection, identification and traceability.

#### References:

FQD 140 - Material Identification and Traceability; FQD 150 - Warehouse Control;

## FQD 160 - Purchasing; FPD 370 - Calibration System

### 4.9 Process Control

G&R Labs will identify and plan calibration procedures for all processes which directly affect quality. Such procedures shall include written work instructions.

Processes should be carried out under controlled conditions. Controlled conditions include the following:

- 1) Calibration procedures defining processes.
- 2) Use of suitable equipment, and a suitable working environment;
- 3) Compliance with reference standards and documented procedures;
- 4) Monitoring and control of product characteristics, when required;
- 5) The approval of procedures.
- 6) Maintenance of equipment to ensure continuing calibration capability.

Instructions, requirements and acceptance criteria for calibration procedures are clearly documented.

The President is required to train personnel on each process and equipment category they are assigned to. Training requirements are defined in section 4.17.

( Reference FPD 370 - Calibration System ; FQD 105 - Training Requirements )

#### 4.9.1 Sales

All sales are controlled to insure timeliness of delivery. These controls apply to invoicing, modifications, storage, shipping, and receiving.

( Reference FQD 106 - Customer Complaints; FQD 140 - Material Identification and Traceability; FQD 150 - Warehouse Control; FQD 160 - Purchasing )

### 4.10 Inspection and Testing

#### 4.10.1 General

Documented procedures will be established and maintained for the inspection and calibration of customer-owned property. Records of calibration will be detailed in documented procedures.

(calibration sheet)

#### 4.10.2 Receiving Inspection and Testing

##### 4.10.2.1 Sales

Calibration meters are inspected for the correct part number and quantity received using G&R Labs Purchase Orders and the packing slips received with the incoming shipment. The calibration technician is responsible for receiving inspection and testing for all products under their control.

G&R Labs will determine the amount and nature of receiving inspection.

##### 4.10.2.2 Service

Customer-owned property is inspected to insure all items received match those listed on the customer's paperwork and that there is no evidence of shipping damage. Calibration technician is responsible for all material under their control. The President has overall responsibility for all test and inspection in the Laboratory and holding area.

#### 4.10.3 Final Inspection and Testing

##### 4.10.3.1 Service Department

Customer-owned property is calibrated to ensure it meets specification. A final inspection of paperwork, equipment labels and cleanliness, and matching of accessories is completed prior to shipping/delivery. This inspection is usually a part of the calibration process and may be recorded by the calibration technician's signature, or stamp, on the Calibration Report.

#### 4.10.4 Test Records

Records will be established and maintained which provide evidence customer-owned property has been tested. Any failure will be handled as nonconforming product in accordance with section 4.13.

#### References:

FQD 141 - Inspection & Test; FPD 370 - Calibration System

## 4.11 Control of Inspection, Measuring and Test Equipment

### 4.11.1 General

Documented procedures will be established and maintained for the control, calibration and maintenance of measuring and test equipment. Records of these inspections will be maintained for audit purposes. This process is the responsibility of the President.

### 4.11.2 Control Procedure

Documented procedures shall:

- 1) Determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision.
- 2) Provide traceability to the National Institute of Standards and Technology (NIST) .
- 3) Identify all measuring and test equipment that affect quality and define calibration and adjustment intervals;
- 4) Define the process used for the calibration of inspection, measuring and test equipment, including details of equipment type, unique identification, frequency of checks, check method, acceptance criteria.
- 5) Identify measuring and test equipment with a suitable indicator or approved identification record to show the calibration status;
- 6) Maintain calibration records for measuring and test equipment;
- 7) Assess and document the validity of previous test results when, measuring and test equipment is found to be out of calibration;
- 8) Ensure that the environmental conditions are suitable for the calibrations, measurements and tests being carried out;
- 9) Ensure that the handling, preservation and storage of measuring and test equipment is such that the accuracy and fitness for the use are maintained (sec. 4.15);
- 10) Protect measuring test hardware and test software from adjustments which would invalidate the calibration setting.

References:

FPD 370 - Calibration System

## 4.12 Test Status

G&R Labs will identify the status of customer-owned property by indicating conformance by using labels. The identification of test status will be maintained to give evidence that the instrument has been calibrated. Responsibility for the Test is that of the calibration technician.

Reference:

FQD 142 - Test Status

## 4.13 Control of Non-Conforming Material

4.13.1 Measurement standards, measuring and test equipment found to be in non-conformance relative to their intended use, are labeled and removed from the work areas to prevent usage.

References: FQD 103 - Control of Non-Conforming Material

## 4.14 Corrective Action

4.14.1. Noted on calibration certificate under the comments section.

## 4.15 Handling, Storage, Packaging and Delivery

### 4.15.1 Handling

Customer-owned property is handled carefully to minimize the chance of damage or alteration of performance.

### 4.15.2 Storage

Storage areas will be designated for the storage of customer-owned property.

### 4.15.3 Packaging

Customer-owned property will be shipped in cardboard boxes with protective packing material. The type and amount of protective packing material is determined by the size and weight of the shipment. Any special packaging requirements specified on the customer's purchasing documents will be followed.

#### 4.15.4 Delivery

Delivery will be arranged to insure the protection of distribution material and customer-owned property. Deliveries are accomplished by one of the following methods:

- ? an approved common carrier
- ? method stipulated by the customer
- ? G&R Labs
- ? customer pick up

#### References:

FQD 150 - Warehouse Control

#### 4.16 Control of Calibration Records

G&R Labs shall establish and maintain all calibration certificates, indexing and filing them under customer name. Responsibility rests with the calibration technician and the office manager.

Calibration records will be maintained to show conformance and effective operation of the quality system.

All Calibration records will be typed. Records will be stored and retained so they are readily available. They will be stored to prevent damage, deterioration and/or loss. Records may be in the form of any type of media, such as hard copy or electronic media.

Certificate retention times will be a minimum of seven years.

#### References:

FQD 112 - Record Control

#### 4.17 Training

G&R Labs will determine training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks will be qualified on the basis of appropriate education, training and/or experience, as required. The importance of training at G&R Labs is reflected in paragraph 4.1.1 of this document - Quality Policy. The President is responsible for training and related documentation.

#### References:

FQD 105 - Training Requirements

#### 4.18 Servicing

Many products depend on regular maintenance, and servicing is specified in the contract. In addition, after market modifications and updates may be required. These activities are normally contractual and the following should be considered:

- ? Service responsibilities among supplier, distributor and user should be clarified;
- ? Service activities should be planned;
- ? Special tools, jigs, parts and measurement and test equipment should be acquired as appropriate;
- ? Provisions should be made for whatever special labor, equipment, parts, documentation, quality procedures, etc., may be required,
- ? Provision should be made for adequate back-up, to include technical advice and support, customer personnel training and Laboratory personnel training;
- ? Plans should be made for corrective and preventative action as required.

#### References:

FQD 180 - Servicing; FPD 370 - Calibration System

#### 4.19 Statistical Techniques

G&R Labs does not have requirements for statistical techniques at this time as existing standards, such as ANSI Z540-1-1994 encourage the use of arbitrary test uncertainty ratios (TURS ) as a means for controlling the penalties associated with inaccurate measurements. In these standards, a TUR of 4:1 is declared to be good enough for the purposes of those invoking the standard.

(A TUR of 4:1 means that the specification limits of the parameter tested must be a least four times greater than the uncertainty of the instrument or system used to measure it.)

As standards change; or if a requirement arises, G&R Labs will establish a system for statistical techniques, especially in the area of statistical methods for inspection and testing. It will be the responsibility of the President to implement and document this process.

G&R Labs realizes that the documentation resulting from the application of statistical methods can be an effective means of demonstrating conformance to requirements for quality, and can be used as a form of quality records.

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