Far West Technology, Inc.

ISO 9001 Quality Manual

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Approval Signatures

President/CEO _____

Executive Vice President _____

Vice President/CFO _____

Change Record

Rev	Date	Responsible Person	Description of Change
0		John Rickey	Initial Release

Controlled Copy Stamp

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The following individuals are on the controlled distribution list:

Copy No.	Signature	Position/Responsibility
1.	_____	President/CEO
2.	_____	Executive Vice President
3.	_____	Vice President/CFO

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Scope

This manual describes system requirements for contracts between Far West Technology (FWT, including the Health Physics Instruments division) and its customer and demonstrates FWT's capability to design and supply product requirements for preventing nonconformity from design through servicing.

This manual provides a description of the quality management system in accordance with the ISO 9001 requirements and serves as a reference for implementing and maintaining FWT's quality management system.

Field of Application

This manual is applicable:

- in contractual situations when the contract, the design effort, and product requirements are stated in performance terms, or need to be established; and
- when product conformance is attained by demonstration of the design, development, production, installation, and service capabilities.

Introduction

Far West Technology, Inc., incorporated in 1971, and its wholly owned subsidiary Health Physics Instruments, Inc. (hereinafter known collectively as FWT), located at 330 South Kellogg Ave., Suite D, Goleta, CA 93117, (phone: 805-964-3615; fax: 805-964-3162), provide radiation detection devices, instruments and services.

Product or Service Overview

FWT manufactures:

?? chemical radiation dosimeters and analysis instrumentation,

?? ion and linear energy transfer chambers,

?? electronic radiation measuring instruments

FWT also provides radiation instrument calibration services

Quality Program

FWT quality policy is communicated throughout the organization by means of inclusion in the employee handbook and display in a prominent location. All employees know and understand the quality program as demonstrated by training.

The Quality Manual is a controlled copy of the FWT quality manual, in accordance with 4.5 Document and Data Control.

4.1 Management Responsibility

4.1.1 Quality Policy

The Quality Policy acknowledges FWT's commitment to Quality and its intent to maintain ongoing compliance with the ISO 9000 standard.

COMPANY QUALITY POLICY

FWT complies with GMP and ISO 9001 to meet or exceed customer's requirements. The success of FWT depends on our commitment to employee involvement, continuous improvement, and improved business performance goals.

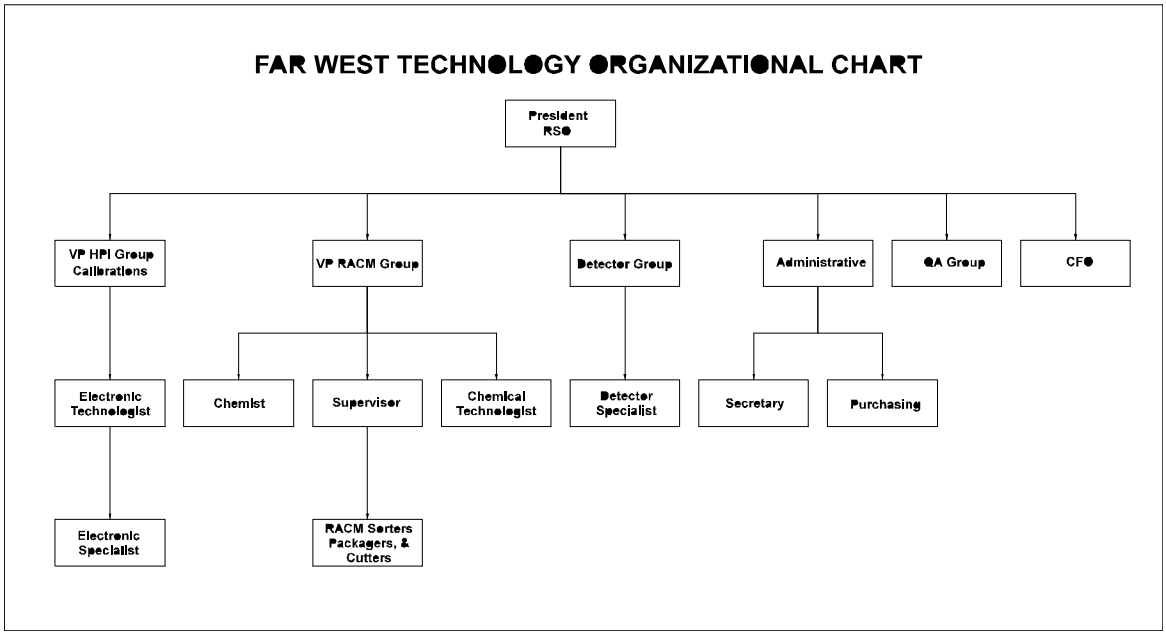
The Quality Policy is relevant to FWT's organizational goals and meets the needs of the customer.

The policy is communicated to employees through inclusion in the employee handbook and display in a prominent location and is endorsed by the signature of the CEO. The policy is reviewed and revised, as required, to reflect FWT's ongoing commitment to Quality and Customer Requirements.

4.1.2 Organization

4.1.2.1 Responsibility and Authority

The organization chart lists management who have the responsibility and authority to ensure that work is managed, performed, and verified in compliance with the ISO 9000 quality standard and customer requirements.



The following employees have the organizational freedom and authority to:

- initiate action to prevent product, process and Quality System non-conformities
- identify and record product, process, and Quality System problems
- initiate, recommend, or provide solutions through designated channels
- verify the implementation of solutions
- control further processing, delivery, or installation of non-conforming product until the deficiency or unsatisfactory condition has been corrected.

The Quality Manager accepts the ultimate responsibility for the overall Quality System and it's operational effectiveness.

The Quality Manager initiates and maintains an organizational structure responsible for the administration of all elements of the Quality System.

The Quality Manager appoints and assigns members the responsibility and authority for ensuring that the Quality System is understood, implemented, and maintained.

Department managers and supervisors have responsibility to:

- act upon, prevent, and record product problems
- provide solutions through designated channels
- verify the implementation of solutions and control further processing, delivery, or installation of non-conforming product until the deficiency or unsatisfactory condition has been corrected

Department managers design, implement, and oversee materials systems and procedures that effectively fulfill the requirements of production.

The Quality Manager makes operational decisions related to quality.

The Quality Manager evaluates the quality program and reports its effectiveness to corporate management.

Quality is every employee's responsibility.

The Quality Manager establishes and implements the Quality Program procedures to comply with the corporate quality requirements.

The President/CEO authorizes the Quality Program.

All employees perform the work, task, or activity to attain quality to the defined standards.

4.1.2.2 Resources

The person verifying quality has authority and organizational freedom to:

- initiate action to prevent product, process and Quality System non-conformities
- identify and record product, process, and Quality System problems

- initiate, recommend, or provide solutions through designated channels

FWT provides adequate resources and trained personnel for verification activities.

Assessments are conducted by members of the Quality Department who are independent of the work being evaluated.

FWT has determined the level of competence, experience, and training necessary to ensure the capability of personnel.

Persons or organizations responsible for defining the acceptability of items or work performed are sufficiently independent from the pressures of production.

FWT has adequate resources essential to implement the quality policies and to achieve its quality objectives. These resources include:

- human resources
- manufacturing equipment
- inspection, test and examination equipment instrumentation and software

This manual further identifies verification resources in the following sections:

- Design Verification Activities section 4.4
- Design Verification Resources section 4.4
- Production Verification Activities section 4.9
- Production Verification Resources section 4.10
- Servicing Verification Activities section 4.19
- Purchasing Verification Activities section 4.4
- Personnel Qualification section 4.18
- Audits section 4.17
- Records section 4.16

4.1.2.3 Management Representative

The management representative is the Quality Manager.

The management representative is responsible for the establishment, implementation, and maintenance of the this American National Standard.

The management representative has the authority and responsibility for ensuring that the requirements of this Manual and the entire Quality System are implemented and maintained.

4.1.3 Executive Management Review

FWT's executive management reviews the quality system annually to assure that ISO 9000 compliance is maintained and continuous improvement is accomplished.

Corrective actions resulting from management reviews are assigned and completed in a timely manner.

The review includes:

- findings of audits

- the overall effectiveness of the quality management system in achieving stated quality objectives
- considerations for updating the quality management system

This policy is supported by the following procedural documents:

Title	**Document Number**
Management Responsibility	**QP-01**

4.2 Quality System

4.2.1 General

The Quality System is documented.

The Quality Manager supports and maintains the quality system and objectives.

The structure of the quality system documentation is:

- level 1 Quality Manual (QM)
- level 2 Quality Procedures (QP-01 to QP-20)
- level 3 Work Instructions

The documentation ensures a controlled quality system.

FWT assures compliance to its quality system through assessment.

4.2.2 Quality-System Procedures

The processes to which the documentation applies are:

- purchasing materials
- manufacturing and production
- inspection and testing
- packaging and storage
- sales
- technical assistance

4.2.3 Quality Planning

FWT documents how quality requirements are met.

The Quality Manager is responsible for preparing quality plans.

Quality plans identify required controls, processes, equipment, fixtures, resources and skills.

Quality plans ensure the compatibility of design, production, installation, servicing, inspection, and testing.

Quality plans include updating test equipment and inspection and testing measures.

This policy is supported by the following procedural documents:

Title	**Document Number**
Quality System	**QP-02**

4.3 Contract Review

4.3.1 General

Customer contracts are reviewed to ensure that customer requirements are adequately defined, documented and understood.

Quality establishes and maintains procedures for contract review.

4.3.2 Review

Department Managers review and approve contracts.

Orders are checked against quotations.

Contracts are reviewed to ensure:

- requirements are adequately defined and documented,
- differences between the contract or accepted order requirements and those in the tender are resolved.
- capabilities to meet the contractual requirements exist.

4.3.3 Amendment to Contract

The customer is made aware of amendments to the contract through verbal or written communications.

Amendments to a contract are communicated to the involved organizational functions through verbal or written communications.

4.3.4 Records

Records of contract reviews are maintained as part of Quality Records.

This policy is supported by the following procedural documents:

Title	**Document Number**
Contract Review	**QP-03**

4.4 Design Control

4.4.1 General

The following design activities are documented:

- identification of input and output variables
- development of design
- testing of design

The documentation includes design control information and design revision.

4.4.2 Design and Development Planning

Product requirements translate customer requirements and expectations into a preliminary set of specifications as the basis for subsequent design work.

Elements included in the product requirements are:

- performance characteristics
- quality assurance and verification

4.4.3 Organizational and Technical Interfaces

R&D verifies that design features are as intended and that authorized design changes have been accomplished and recorded.

Quality validates computer systems and software and interfaces with other departments with design and development responsibility.

R&D provides initial product requirements, performance target values, and market utility assessments.

R&D ensures the availability of products, services and personnel required for the manufacturing and testing of the product.

4.4.4 Design Input

R&D identifies and documents the design input requirements of the product and resolves conflicting, ambiguous, or incomplete requirements with those responsible for drawing up these requirements.

Department managers ensure contract requirements with customers are considered in the design.

4.4.5 Design Output

The design output is documented and verified against input requirements.

The design output describes the validation criteria in terms of design input requirements and acceptance criteria.

The design output references and identifies characteristics of the design that are crucial to the safe and proper functioning of the product.

Quality reviews the design output prior to release.

4.4.6 Design Review

Formal design reviews are conducted.

Quality reviews and approves all new product specifications and drawings prior to release for manufacture.

Records of reviews are maintained as Quality Records.

R&D is responsible for maintaining the record and review of all changes and modifications to the design of the product.

The review includes:

- verification of specifications, drawings and procedures
- generation of documentation and records
- development of acceptance criteria prior to release for manufacturing

4.4.7 Design Verification

A final review is conducted prior to release to ensure that the design-stage output meets the design-stage input requirements.

The design verification includes testing and documentation of the tests.

4.4.8 Design Validation

The design is validated to ensure that the product conforms to the customer's requirements.

The validation includes:

- availability and adequacy of installation, operation, maintenance and repair manuals
- certification of the satisfactory completion of qualification tests

4.4.9 Design Changes

Design changes are given the same review as the initial design, and authorized by the same staff.

This policy is supported by the following procedural documents

Title	**Document Number**
Design Control	**QP-04**

4.5 Document and Data Control

4.5.1 General

The following types of data and documents are controlled:

- Quality Manual
- Quality Procedures
- Work Instructions
- Mechanical and Electrical Drawings

Quality is responsible for document and data control.

Documents require authorized release and revision control

FWT ensures proper operation of the document control system internal assessment.

4.5.2 Document Approval and Issue

Prior to issue, quality system documents are reviewed and approved.

A master list of all controlled documents identifies the current revision level.

Policy and procedure documents have unique identifiers.

Obsolete documents are removed from all points of use and either destroyed or clearly marked as obsolete.

4.5.3 Document and Data Changes

Quality reviews and approves changes to procedures, instructions, and documents.

This policy is supported by the following procedural documents:

Title	**Document Number**
Document and Data Control	**QP-05**

4.6 Purchasing

4.6.1 General

FWT has documentation to ensure that all products and services purchased from its subcontractors conform to specified requirements.

Records of purchasing activities are maintained as part of Quality Records.

4.6.2 Evaluation of Subcontractors

Subcontractors are selected based on:

- ability to meet contract and quality requirements
- product type

FWT maintains a list of approved subcontractors.

Quality re-evaluates and updates qualified subcontractors.

4.6.3 Purchasing Data

Quality or Department Managers issue specifications and monitors the subcontractor's performance.

Purchasing documents ensure the product ordered is clearly described.

The following information is included in the purchase document:

- Vendor name
- Purchase order number and date
- identification of the product
- quantity ordered and price

4.6.4 Verification of Purchased Product

FWT verifies the conformance of purchased product.

This verification involves examination and acceptance of the items upon delivery.

Products and services found to be non-conforming are held and appropriately labeled pending resolution of the problem with the sub-contractor.

4.6.4.1 Supplier Verification at Subcontractor's Premises

Quality assesses subcontractor performance and completes an Assessment Report.

Assessment Reports are maintained as a Quality Record.

4.6.4.2 Customer Verification of Subcontracted Product

When required by contract, FWT arranges visits of subcontractors by customers.

Customers of FWT are provided the right to verify the product produced by the subcontractor and the conditions under which such product is manufactured.

This verification does not absolve FWT of the responsibility to provide acceptable products.

This policy is supported by the following procedural documents:

Title	**Document Number**
Purchasing	**QP-06**

4.7 Control of Customer Supplied Product

FWT maintains customer supplied product from receipt through delivery to ensure customer requirements are met.

Records of all customer supplied product are maintained as part of Quality Records.

Customer supplied products are stored and maintained in a manner which prevents damage or deterioration.

Customer supplied product received in a non-conforming or damaged condition is reported to the customer.

This policy is supported by the following procedural documents:

Title	**Document Number**
Customer Supplied Product	**QP-07**

4.8 Product Identification and Traceability

FWT maintains methods to identify product, as it relates to quality, to ensure customer requirements can be met.

Traceability is maintained when required by customer contract.

Quality is responsible for assuring that product identification and traceability standards are maintained.

To identify materials, parts, components, and products, FWT uses lot (or batch) numbers or serial numbers.

Records are kept for individual products or batches.

Procedures for identification and control of such items ensure:

- only correct and acceptable items or materials are used in fulfilling customer orders
- measures are taken to assure that time-dated, shelf life materials are adequately controlled
- methods exist to identify, segregate, and dispose of non-conforming items, and to remove such items from storage and manufacture.

This policy is supported by the following procedural documents:

Title	**Document Number**
Product ID and Traceability	**QP-08**

4.9 Process Control

FWT controls processes critical to product and service quality.

Any employee is responsible for stopping any operation that is not in control.

Processes are controlled using sampling plans, statistical analysis or process control methods.

The manufacturing process is monitored and controlled at all operations that may affect the final product quality.

Records are maintained for qualified processes and equipment as part of Quality Records.

The documentation:

- identifies processes which are performed by qualified personnel using approved, written procedures and controlled equipment
- ensures processes are monitored and controlled, where appropriate
- provides detailed procedures for specific operations.

FWT monitors product and process characteristics which are critical to customer requirements.

Equipment is approved and qualified for use.

Employees are trained using documented procedures and work instructions, written standards, representative samples or illustrations.

This policy is supported by the following procedural documents:

Title	**Document Number**
Process Control	**QP-09**

4.10 Inspection and Testing

4.10.1 General

FWT has established documented procedures to ensure that products are inspected and tested for compliance to specifications.

FWT has procedures for inspection and testing at appropriate points in the manufacturing process.

FWT evaluates the test results to verify satisfactory performance.

Where required by customer contract, specified hold points and inspection or test points are identified.

Test results are analyzed, reviewed, and communicated to the department manager for appropriate action.

4.10.2 Receiving Inspection and Testing

4.10.2.1 Non-conforming Material

Prior to release to manufacturing or shipment to customers, material received from subcontractors is verified.

Material which cannot be inspected and tested at the time of receipt is tracked through the process for immediate recall, if required.

Material found to be non-conforming in the inspection and test process is clearly labeled and segregated.

4.10.2.2 Verification Requirements

Receiving inspection is performed on material used in the manufacturing of products.

Verification requirements for incoming product is in QP-10.

4.10.2.3 Released Product

Incoming product released for urgent production prior to verification is positively identified with a tag indicating the lack of verification.

A Quality Record for the released product is maintained, in the event of recall and replacement due to nonconformity.

4.10.3 In-process Inspection and Testing

Product manufactured at FWT is monitored through process inspection points and test stations.

Department Managers generate tests to verify design and manufacturing capabilities.

Trained personnel perform routine manufacturing tests and Department Managers verify the results.

4.10.4 Final Inspection and Testing

Required inspections and test are completed, documented, and authorized prior to shipment of product to customers.

4.10.5 Inspection and Test Records

Adequate records of inspection, audit inspections, tests, and examinations are maintained as:

- part of Quality Records
- evidence of compliance
- for use in corrective action activities

This policy is supported by the following procedural documents:

Title	**Document Number**
Inspection and Testing	**QP-10**

4.11 Control of Inspection, Measuring, and Test Equipment

4.11.1 General

Controls are established to maintain the integrity of equipment used in inspection, measuring, and testing of products.

Quality schedules, calibrates, and maintains inspection, measuring and test equipment whether owned, rented, or provided by the customer to ensure conformity of products to specifications with the required measurement capability.

Calibration is traceable to national standards.

FWT maintains individual calibration records of all inspection, measurement, and test equipment as Quality Records.

FWT provides employees with training in the handling, storage, and use of inspection, measurement, and test equipment, where required.

Safeguards against inadvertent adjustments to equipment, hardware, and software are used when applicable.

Inspection, measurement, and test equipment found to be out-of-tolerance is immediately removed from service until the out-of-calibration condition is corrected.

4.11.2 Control Procedure

FWT ensures that:

- devices used for verification of quality are the appropriate type and accuracy and are verified at intervals based on purpose and usage
- a device's calibration status is clearly identified
- environmental conditions are suitable for calibrations, inspections, measurements and tests being carried out

This policy is supported by the following procedural documents:

Title	**Document Number**
Inspection, Measuring and Test Equipment	**QP-11**

4.12 Inspection and Test Status

4.13.1 General

FWT monitors and controls the inspection and test status of:

- raw materials
- work-in-process
- finished goods

Documented procedures indicate the inspection and test status using markings or physical location.

Non-conforming materials are segregated by distinctive markings or location.

Inspection and test status records are maintained as part of Quality Records.

Department Managers are responsible for ongoing maintenance of the inspection and test status of products within the assigned area throughout FWT.

Personnel are trained to maintain all inspections and test status.

This policy is supported by the following procedural documents:

Title	**Document Number**
Inspection and Test Status	**QP-12**

4.13 Control of Non-conforming Product

4.13.1 General

FWT maintains a system to monitor and detect non-conforming material to prevent its use or shipment to customers.

Reviews of non-conforming material are maintained as part of Quality Records.

4.13.2 Review and Disposition of Non -conforming Product

Department Managers have the responsibility for control of non-conforming material.

Any employee has the authority to stop manufacturing and/or shipment of any material found not to meet customer requirements.

Documented procedures cover how to identify, evaluate, segregate and disposition non-conforming product.

Disposition of non-conforming material ensures that all aspects and implications of the issue are considered.

Dispositions are:

- repair or rework
- return to supplier
- scrap

Repaired or reworked product is re-inspected prior to release to a customer.

Appropriate personnel are notified of non-conforming material found during in-process and final inspection procedures.

FWT notifies the customer of potential material or product nonconformity and takes necessary action to recall the material for correction.

Causes of non-conformance are investigated.

Records of corrective actions resulting from the review of non-conforming materials are maintained and analyzed.

This policy is supported by the following procedural documents:

Title	**Document Number**
Control of Non-conforming Product	**QP-13**

4.14 Corrective and Preventive Action

4.14.1 General

Corrective and preventative actions apply to all processes and procedures.

FWT maintains a preventive and corrective action log.

These records are used to assess the effectiveness of the program.

Quality is responsible to record, assign, track, verify, and close all preventive and corrective actions.

Corrective and preventive actions are reported to Management.

4.14.2 Corrective Action

FWT maintains a corrective action system to identify, correct and prevent recurrence of nonconformity and deficiencies.

The following are reviewed for corrective action:

- customer complaints
- internal product and process reviews

Any employee can initiate a corrective action.

The root cause is analyzed to prevent recurrence, such as procedures, instructions, training, drawings, etc.

Action steps are defined to be implemented to correct conditions adverse to quality.

Corrective actions are evaluated to ensure they are effective.

4.14.3 Preventive Action

FWT maintains a preventive action program to define, improve upon and eliminate potential causes of non-conforming product.

To eliminate potential causes of non-conforming product or process, FWT analyzes work processes and procedures, quality records, audit results and customer complaints.

All employees can initiate preventive action.

Procedures document the steps needed to deal with problems requiring preventive action.

This policy is supported by the following procedural documents:

Title	**Document Number**
Corrective and Preventative Action	**QP-14**

4.15 Handling, Storage, Packaging, Preservation, and Delivery

4.15.1 General

FWT maintains documented procedures to control the handling, storage, packaging, preservation, and delivery of all materials.

FWT verifies adherence to handling, storage, packaging, preservation, and delivery procedures through internal assessments.

4.15.2 Handling

Employees are trained in the proper handling of materials and in the maintenance of material storage environments.

Specific training is provided for the handling of hazardous materials and radioactive materials.

4.15.3 Storage

Designated storage areas are used to protect all materials from damage or deterioration prior to use or delivery.

4.15.4 Packaging

Authorized personnel package product.

Packaging and identification of finished material allow for ready identification of finished material.

Training is provided in the proper packaging, packing, and marking.

4.15.5 Preservation

Appropriate methods of preserving and segregating product are implemented and communicated.

4.15.6 Delivery

FWT protects the quality of product after final inspection and test.

Where contractually specified, FWT is responsible for packaging and preservation during transit including delivery to destination.

This policy is supported by the following procedural documents:

Title	**Document Number**
Handling, Storage, Packaging, Preservation, and Delivery	**QP-15**

4.16 Quality Records

FWT has an established process for the control of Quality Records including identification, collection, indexing, filing, storage, maintenance and disposition.

Quality Records permit analysis of conditions found to be adverse to quality, such as qualification of personnel, procedures and equipment.

Quality Records are:

- legible
- stored in a suitable environment to prevent damage, deterioration or loss
- retained for established period of time
- readily retrievable

Quality is responsible for the proper maintenance of Quality Records.

This policy is supported by the following procedural documents:

Title	**Document Number**
Quality Records	**QP-16**

4.17 Internal Quality Audits

At least annually, FWT performs scheduled audits of activities which affect quality to ascertain the effectiveness of its Quality system.

Quality is responsible for ensuring that audits of FWT's Quality System are conducted.

An internal audit plan specifies frequency, scope and auditors.

Audits are conducted by personnel independent of those having direct responsibility for the activity being audited.

Requests for corrective action, if any, resulting from the internal audit are processed in accordance with Internal Quality Audits

Quality reviews and verifies corrective action resulting from audits.

Areas are re-audited to verify the effectiveness of the corrective action.

Audit results are reported to the Management Representative and submitted to executive management for review.

Audit results are maintained as part of Quality Records.

This policy is supported by the following procedural documents:

Title	**Document Number**
Internal Quality Audits	**QP-17**

4.18 Training

FWT employees have the education, experience, and training to produce products and services to meet all customer requirements.

The following type of training is provided:

- on the job training
- instruction for each operation relative to the use of equipment
- classroom instruction
- safety training

Training establishes an employee's competence to meet the requirements of the Quality System.

Every employee is made aware of the company's quality policies as part of the training program.

Department Managers are responsible for identifying tasks to be performed to meet customer requirements.

Department Managers are responsible for determining training needs for personnel.

Department Managers are responsible for ensuring that timely training is provided.

Department Managers are responsible for budgeting sufficient funds to adequately train employees.

Every employee involved in the quality system has a training record.

Employee training records are maintained as a part of Quality Records.

Department Managers maintain job descriptions.

This policy is supported by the following procedural documents:

Title	**Document Number**
Training	**QP-18**

4.19 Servicing

FWT has established processes to provide customers with post-sales services.

Services to meet customer requirements are made available through technical assistance.

FWT maintains records of all services provided as part of Quality Records.

This policy is supported by the following procedural documents:

Title	**Document Number**
Servicing	**QP-19**

4.20 Statistical Techniques

4.20.1 Identification of Need

Department Managers are responsible for the selection and use of appropriate statistical techniques to ensure customer requirements and company quality standards are achieved.

FWT uses statistical methods to measure the acceptability of process capability and product characteristics

4.20.2 Procedures

FWT has established documented procedures to measure, monitor, and improve products and processes by the use of statistical techniques.

Documentation of statistical techniques is maintained as part of Quality Records.

Employees are trained in the proper use of statistical techniques.

This policy is supported by the following procedural documents:

Title	**Document Number**
Statistical Techniques	**QP-20**