

GRAFTEL, Inc.

QUALITY ASSURANCE MANUAL



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Revision 4
April 1, 2006

SERVICING YOUR ENGINEERING, INSTRUMENTATION, & CALIBRATION NEEDS

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Revisions Listing

Revision 3

Full revision to allow compliance with ISO 17025-1999

Revision 4

Revision to allow compliance with ISO 17025-2005

To many changes to allow for use of vertical bars. Specific changes shall instead be listed below.

Change references from ISO 17025-1999 to ISO 17025-2005 everywhere

Section affected:	1	Changed to comply with section 4.1.5.k Added words from section 4.2.2.e
	1.1	Sections added to include 4.1.6, 4.2.3, 4.2.4, 4.2.7 and 4.10
	2.3	Changed to comply with section 4.1.5.a
	4.4	Added section 4.4.3 to include requirements from section 4.12.1
	4.5	Added requirements from section 5.2.2
	9.5	Added this new section to include the guidance from section 4.7.2
	16.7.5	Added requirement from section 5.9.2
	18.6	Added requirements from section 4.2.2 and 4.15.1

1 SCOPE AND FIELD OF APPLICABILITY

Graftel, Inc., is an Illinois corporation engaged in consulting, calibration, testing and procurement of components, systems and services. Graftel is committed to providing high quality calibration and consulting services through the application of good laboratory practices and adherence to this quality program.

This Quality Assurance Program has been developed to ensure that all quality related work performed by Graftel will be in compliance with the applicable provisions of ISO/IEC 17025-2005 and ANSI/NCSL Z540-1-1994. Compliance may include 10CFR 50 Appendix B with part 21 applicable, only when invoked by the customer and agreed to by Graftel. All calibrations are traceable to the National Institute of Standards and Technology, (NIST). All applicable requirements from ISO 9001 and 9002 are also met and exceeded. Graftel's management is committed to continually improve the effectiveness of the management system.

Attachment A contains a cross-reference between this document and ISO/IEC 17025-2005. Attachment B contains a cross-reference between ISO/IEC 17025-2005 and ISO 9001 & ISO 9002 to demonstrate this manual's compliance.

Three levels of written documents are used. The Quality Assurance manual is the top-level document. For each section in this manual, there may correspond one or more Graftel administrative procedure(s), (GAPs). The GAP number will correspond to the section number of this manual to which it applies. The lowest level documents are the Graftel Implementing Procedures, (GIPs) and Graftel Test Procedures (GTPs). These provide instructions for the performance of specific activities. In the event of a conflict between the requirements of the Quality Assurance Program and other procedural documents, the Quality Assurance Program shall take precedence.

All Graftel personnel assigned to any quality related work must be fully familiar with the provisions of the Quality Assurance Program. They must also be aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system. The Quality Assurance Program shall be fully implemented in any and all work under the direct supervision and control of Graftel. This includes activities carried out in the company's permanent facilities as well as at remote sites.

Employees of Graftel, its subcontractors and consultants, who are assigned to work under the direct supervision and control of client personnel, shall be considered by Graftel to be loan servants, whether they are classified by the client as consultants, contractors, or loan servants. It is Graftel's policy that such employees shall perform their work under the client's Quality Assurance Program.

The Quality Assurance Manager is responsible for implementing the Quality Assurance Program and maintaining quality standards by ensuring compliance with this program's provisions. Only items and services to be used in quality related applications need to fall under the requirements of this manual. Other items and services may be included at the discretion of the president or as required by customer purchase specifications.

1.1 Quality Policy Statement

Graftel, Inc. 870 Cambridge Drive

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Graftel, Inc. has been a supplier of products and services since 1991. Our success in large part has been based on understanding, promoting, and delivering the highest quality products and services to our customers. Our "Quality First" philosophy applies to every aspect of our business. Each Graftel, Inc. employee is empowered to resolve all quality and customer service issues promptly by completely utilizing any and all resources necessary.

The objective of our quality system is that our entire organization must be committed to the solitary goal of providing our customers with unparalleled quality products and services. To this end, it is the responsibility of Graftel, Inc. management and personnel to:

- conduct business with the highest commitment to quality services, best professional practices, and customer satisfaction.
- promote the highest ethical standards within the organization.
- ensure that Graftel, Inc. Quality Policy and procedures are effectively communicated, understood, implemented, and maintained at all levels of the organization.
- provide the working environment that will allow employees to achieve their maximum career potential.
- maintain an open dialogue between all levels of the organization to promote new ideas that will increase productivity, quality, or customer satisfaction.
- familiarize themselves with ISO 17025-2005, ANSI/NCSL Z540-1-1994 and implement the policies and procedures of this standard in their work
- avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity.

Graftel shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

Graftel shall make reasonable efforts to afford clients or their representatives' cooperation to clarify the client's request to monitor the laboratories performance in relation to the work performed while at the same time ensuring the confidentiality of other clients.

Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system. They shall also provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness. Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory regulatory requirements. They shall also ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

2 ORGANIZATION

2.1 Purpose

This section specifies Graftel's organization and how it interfaces with and manages the Quality Assurance Program.

2.2 Structure of the Organization

Figure 2.1 shows Graftel's organization structure.

2.3 Responsibilities and Authority

The responsibilities and authorities for Graftel, Inc. personnel who manage, perform, or verify work affecting quality are listed below along with their job descriptions. Graftel, Inc. personnel shall be free from undue internal, external, commercial, financial and other pressures that might adversely affect the quality of their work. They shall have direct access to responsible management at a level where appropriate action may be effected.

These personnel shall have sufficient authority, resources, access to work areas, and organizational independence to:

- identify quality problems,
- initiate, recommend, or provide solutions to quality problems by initiating actions to prevent or to minimize these problems,
- verify implementation of solutions,
- ensure that further testing, processing, delivery, installation, or use is controlled until proper disposition of a non-conformance, deficiency, or unsatisfactory condition has occurred.
- implement, maintain and improve the management system.

Staff positions, key management personnel and their alternates or deputies are listed below.

- President

The president is responsible for all aspects of Graftel business. The alternate is the Vice President of Marketing and Sales.

- Vice President of Marketing and Sales

The Vice President of Marketing and Sales oversees all sales and financial aspects of corporate operations. Areas of responsibility include shipping and logistics, allocation of assets and resources, invoicing, payments, and capital asset purchases. This position reports to the President. The alternate is the Manager of Projects and Engineering.

- Quality Manager

The Quality Manager is responsible for the maintenance of the overall Graftel, Inc. quality program. This program includes ISO 17025 accreditation. Areas of responsibility include review and revision of the quality manual, procedures, audits (internal and external), implementation of procedures that ensure Graftel, Inc. Instrument's conformance to ISO 17025-2005, ANSI/NCSL Z540-1-1994 and documented customer quality requirements such as 10-CFR 50 Appendix B Part 21 only when invoked. Change control of the quality manual, is maintained by the Quality Manager. The Quality Manager coordinates requests for, follow up, corrective action, and analysis of quality data. The Quality Manager will appoint a deputy to cover quality responsibilities in his absence. This position reports to the President. The alternate is the President.

- Manager of Projects and Engineering

The Manager of Projects and Engineering has responsibility and authority for technical operations, calibration, equipment evaluation/selection, technical training, technical support and traceability. The Manager of Projects and Engineering is responsible for selecting arranging and coordinating participation in inter-laboratory comparison programs. The Manager of Projects and Engineering may have other duties and responsibilities in addition to this position. The duties of the Manager of Projects and Engineering shall be assumed by an alternate when the Manager of Projects and Engineering is unavailable. The Manager of Projects and Engineering reports to the President. The alternate is the President.

- Lead Service Technician

The Lead Service Technician is responsible for the overall direction and administration, of the production activities for their department within the calibration laboratory. They are also responsible for the implementation and execution of the quality system within their department, and shall ensure that service and support personnel are trained and qualified to perform their assigned duties. The Lead Service Technician is responsible for the timely implementation of corrective and preventive actions and for ensuring that customers are notified, when applicable, of system deviations, failures, and deficiencies. The Lead Service Technician administers storage areas within the laboratory. The Lead Service Technician reports directly to the Manager of Projects and Engineering. The alternate is the Manager of Projects and Engineering.

- Document Control Coordinator

The Document Control Coordinator maintains, catalogs, and controls the distribution of all documents which are important to quality activities. The Document Control Coordinator reports to the Manager of Projects and Engineering. The alternate is the Manager of Projects and Engineering.

- Technical Staff

Laboratory technicians report to Lead Service Technician. Personnel are directly responsible for the quality of their work, and adherence to documented Graftel, Inc. Policies and Procedures.

- **Support Staff**

Support staff is directly responsible for the quality of their work, and adherence to documented Graftel, Inc. Policies and Procedures. Support Staff report directly to the Manager of Projects and Engineering.

- **Sales Staff**

The sales staff is responsible for promoting the sales of Graftel products and services. The sales staff reports to the Vice President of Marketing and Sales.

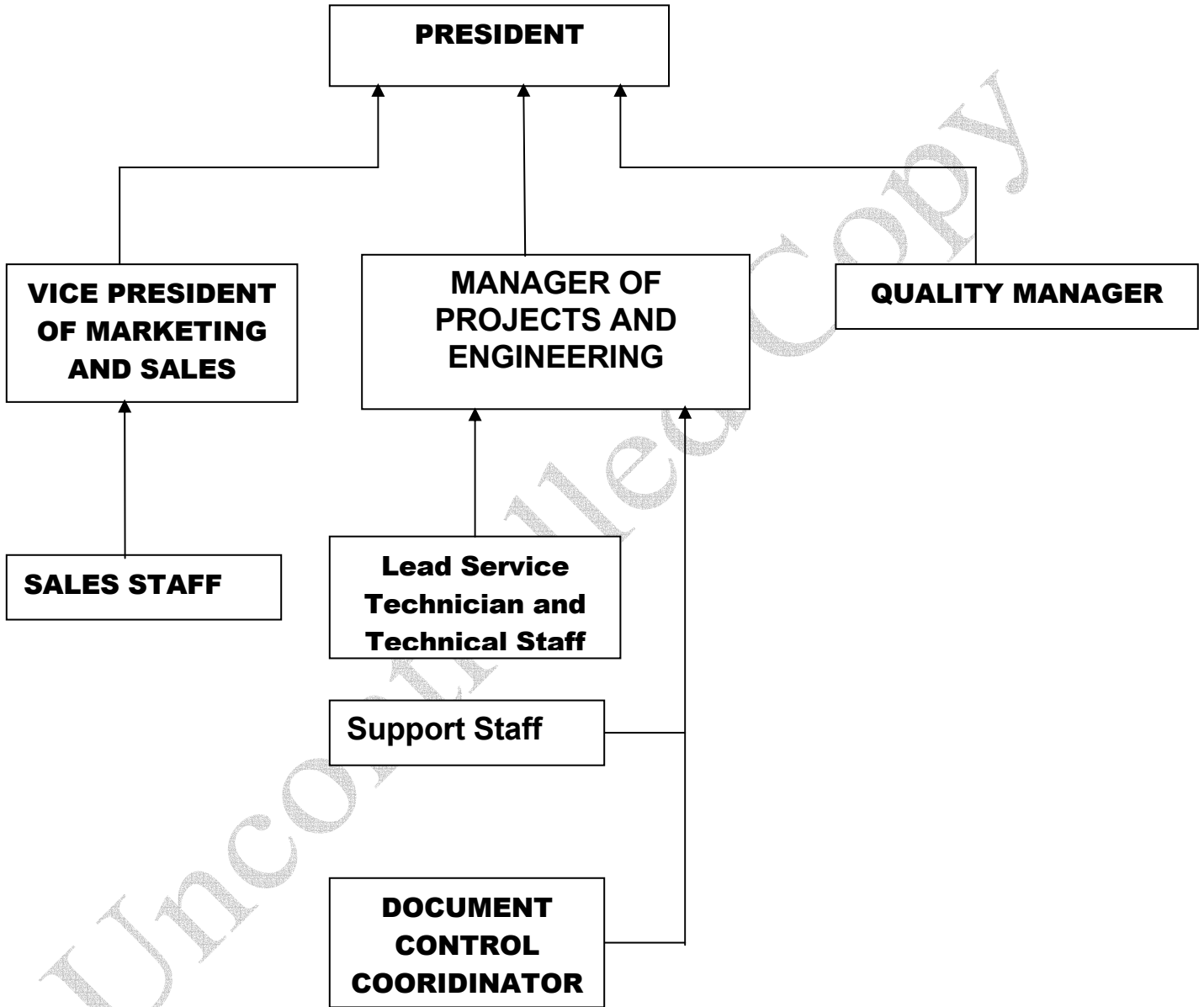
2.4 Personnel Responsibilities

The responsibility for tasks outside of job descriptions shall be documented using letters or memorandums. The letter or memorandum must identify the task(s) or object(s) being delegated, date of delegation, names of the originator and recipients'. Letters of delegation will be retained in the personnel files of the individuals. Superseded letters of delegation will be removed and destroyed.

Graftel, Inc. personnel will alert their immediate supervisor of all situations that could impact quality. Graftel, Inc. management will document the situation and initiate the appropriate action(s). Graftel, Inc. personnel have the authority to bring their concerns to the next level of management if their direct manager or supervisor fails to respond to their documented concerns.

Figure 2.1

GRAFTEL ORGANIZATION STRUCTURE



3 DEFINITIONS

Included below are the definitions of certain quality-related terms used by Graftel, Inc.

<u>Acceptance Criteria</u>	Specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other requirement documents.
<u>Anomaly</u>	A deviation from established requirements, methods, or sequence, or a malfunction or other conditions which may influence test data or test performance.
<u>Approval</u>	An act of endorsing or adding positive authorization, or both.
<u>As-Built Data</u>	Documented data that describes the condition actually achieved in a product.
<u>Assembly</u>	A combination of subassemblies or components, or both, fitted together to form a unit.
<u>Audit</u>	A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.
<u>Basic Component</u>	When applied to nuclear power application means a structure system, component or part thereof necessary to assure operation in a nuclear safety-related function. Basic component, in all cases, includes safety related design, testing, inspection, analysis, fabrication, replacement parts, or consulting services important to safety that are associated with the component hardware.
<u>Certificate of Conformance</u>	A written statement, signed by a qualified party, certifying that items or services comply with specific requirements.
<u>Certificate of Compliance</u>	A written statement, signed by a qualified party, attesting that the items or services are in accordance with specified requirements and accompanied by additional information to substantiate the statement.
<u>Certified Test Report</u>	A written and signed document, approved by a qualified party, which contains sufficient data and information to verify the actual properties of items and the actual results of all required tests.

<u>Certification</u>	The action of determining, verifying, and attesting, in writing, to the qualifications of personnel or material.
<u>Characteristic</u>	Any property or attribute of an item, process or service that is distinct, describable, and measurable, as conforming or non-conforming to specified quality requirements. Quality characteristics are generally identified in specifications and drawings, which describe the item, process, or service.
<u>Checks</u>	The tests, measurements, verifications, or controls placed on an activity by means of investigations, comparisons, or examinations, to determine satisfactory condition, accuracy, safety, or performance.
<u>Cleanness</u>	A state of being clean in accordance with predetermined standards that usually implies freedom from dirt, scale, heavy rust, oil, or other contaminating impurities.
<u>Commercial Grade Item</u>	An item satisfying (a), (b) and (c) below: (a) Not subject to design or specification requirements that are unique to nuclear facilities; (b) Used in applications other than nuclear facilities; (c) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).
<u>Computer Program</u>	A sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution as well as to execute it.
<u>Component</u>	A piece of equipment which will be combined with other components to form an assembly.
<u>Condition Adverse Quality</u>	An all-inclusive term used in reference to any of the following: to failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one, which, if uncorrected, could have a serious effect on safety or operability.
<u>Contaminants</u>	Foreign materials such as mill scale, dirt, oil, chemicals, and any matter that renders a fluid, solid, or surface impure and unclean according to preset standards of acceptable cleanliness.

<u>Contractor</u>	Any organization under contract for furnishing items or services. It includes the terms Vendor, Supplier, Subcontractor, Fabricator, and sub-tier levels of these where appropriate.
<u>Corrective Action</u>	Measures taken to rectify conditions adverse to quality and where necessary to preclude repetition.
<u>Defective Material</u>	A material or component, which has one or more characteristics that, does not comply with specified requirements.
<u>Design Change</u>	Any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.
<u>Design Input</u>	Those criteria, parameters, bases, or other design requirements upon which detailed final design is based.
<u>Design Output</u>	Drawings, specifications, and other documents used to define technical requirements of structures, systems, components, and computer programs.
<u>Design Process</u>	Technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.
<u>Deviation</u>	A nonconformance or departure of a characteristic from specified requirements.
<u>Documentation</u>	Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures or results.
<u>Examination</u>	An element of inspection consisting of investigation of materials, components, supplies, or services to determine conformance to those specified requirements which can be determined by such investigation. Examination is usually nondestructive and includes simple physical manipulation, gaging, and measurement.
<u>External Audit</u>	An audit of those portions of another organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization.
<u>Final Design</u>	Approved design output documents and approved changes thereto.
<u>Guidelines</u>	Particular provisions considered good practice but which are not mandatory in programs intended to comply with regulatory requirements. The term "should" denotes a guideline while "shall" denotes a mandatory requirement.

<u>Handling</u>	An act of physically moving items by hand or mechanical means, but not including transport modes.
<u>Indoctrination</u>	Instruction or reading requirements to familiarize personnel in basic principles or elements or a fundamental skill.
<u>Inspector</u>	A qualified individual whose duties include the verification of quality-related activities or installations, or both.
<u>Inspection</u>	A phase of quality control which by means of examination, observation, or measurement determines the conformance of materials, supplies, components, parts, appurtenances, systems, processes, or structures to predetermined quality requirements.
<u>Internal Audit</u>	An audit of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.
<u>Item</u>	Any level of unit assembly, including structure, system, subsystem, subassembly, component, part, or material.
<u>Manufacturer</u>	One who constructs any class of component, part, or appurtenance to meet prescribed design requirements.
<u>Material</u>	A substance or combination of substances forming components, parts, pieces, and equipment items, including machinery, castings, liquids, formed steel shapes, aggregates, and cement.
<u>Measurement and Test Equipment</u>	Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or to acquire data to verify conformance to specified requirements.
<u>(M&TE)</u>	Measurement and Test Equipment. Equipment that is used to Measure or Test characteristics of a system to determine if that system conforms to predetermined specifications.
<u>Modification</u>	A planned change in design or operation accomplished in accordance with the requirements and limitations of applicable codes, standards, specifications, and predetermined safety restrictions.
<u>Nonconformance</u>	A deficiency in characteristic, documentation, or procedure that renders the qualifications of an item unacceptable or indeterminate. Examples of nonconformance include physical defects; test failures; incorrect or inadequate documentation; or deviation from prescribed processing, inspection, or test procedures.

<u>Objective Evidence</u>	Any statement of fact, information, or record, either quantitative or qualitative, pertaining to the quality of an item or service based on observations, measurements, or tests, which can be verified.
<u>Package</u>	A wrapping or container including its contents of material or equipment.
<u>Part</u>	An item, which has work, performed on it and which is attached to and becomes part of a component before completion of the component.
<u>Procedure</u>	A document that specifies or describes how an activity is to be performed. It may include methods to be employed, equipment or materials to be used, and sequence of operations.
<u>Procurement</u>	Documents that identify and define the requirements that <u>Documents</u> components or services must meet in order to be considered acceptable by purchaser
<u>Project</u>	A planned series of activities including all actions necessary to provide, utilize, and maintain a facility or portion thereof.
<u>Purchaser</u>	The organization responsible for establishment of procurement requirements and for issuance, administration, or both, of procurement documents.
<u>Qualification</u>	The characteristics or abilities gained through training or experience or both that enables an individual to perform a required function.
<u>Qualified Party</u>	A person or organization competent and recognized as knowledgeable to perform certain functions.
<u>Qualified Procedure</u>	A procedure that incorporates all applicable codes and standards, manufacturers' parameters, and engineering specifications and has been proven adequate for its intended purpose.
<u>Quality Assurance</u>	All those planned and systematic actions necessary to provide adequate
<u>(QA)</u>	confidence that a structure, system or component will perform satisfactorily in service.
<u>Quality Assurance Record</u>	A completed document that furnishes evidence of the quality of items and/or activities affecting quality.

<u>Quality Control</u>	Those quality assurance actions that provide a means to control and measure the characteristics of an item, process, or facility to established requirements.
<u>Receiving</u>	Taking delivery of an item at a designated location.
<u>Repair</u>	The process of restoring a non-conforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still may not conform to the original requirement.
<u>Report</u>	A written document that gives information for record purposes.
<u>Rework</u>	The process by which a non-conforming item is made to conform to a prior specified requirement by completion, re-machining, reassembling, or other corrective means.
<u>Right of Access</u>	The right of a purchaser or designated representative to enter the premises of a supplier for the purpose of visitation, inspection, surveillance, or quality assurance audit.
<u>Safety Related</u>	The name applied to structures, systems, components, materials, services, or activities within a nuclear power plant to ensure the integrity of the reactor coolant pressure boundary, the capability to effect a safe reactor shutdown, the capability to prevent or mitigate an accident with potential for exposure, and the operation of the facility within technical specification limits or federal regulations.
<u>Service</u>	The performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation.
<u>Source Surveillance</u>	A review, observation, or inspection for the purpose of verifying that an action has been accomplished as specified at the location of material procurement or manufacture.
<u>Special Process</u>	A process, the results of which are highly dependent on the control of the process or the skill of the operators or both and in which the specified quality cannot be readily determined by inspection or test of the product.
<u>Specification</u>	A concise statement of a set of requirements to be satisfied by a product or process indicating, whenever appropriate, the procedure by means of which it may be determined whether the requirements given are satisfied.
<u>Standard</u>	The result of a standardization effort approved by a recognized authority.

<u>Storage</u>	The act of holding items prior to use for their ultimate function.
<u>Subsystem</u>	A group of components combined to perform a single function.
<u>Supplier</u>	Any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their sub-levels.
<u>Surveillance</u>	The act of monitoring or observing to verify whether an item or activity conforms to specified requirements.
<u>System</u>	A group of subsystems united by some interaction or interdependence, performing many duties but functioning as a single unit.
<u>Testing</u>	The determination or verification of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.
<u>Traceability</u>	The ability to trace the history, application, or location of an item or activities by means of recorded identification.
<u>Training</u>	Instruction provided to personnel to develop and demonstrate initial proficiency in the application of selected requirements, methods, and procedures, and to adapt to changes in technology, methods.
<u>Use-As-Is</u>	A disposition which may be imposed for a nonconformance when it can be established that the discrepancy will result in no adverse conditions and that the item under consideration will continue to meet all engineering functional requirements including performance, maintainability, fit, and safety.
<u>Verification</u>	An act of confirming, substantiating, and assuring that an activity or condition has been implemented in conformance with the specified requirements.

4 THE QUALITY ASSURANCE PROGRAM

4.1 Purpose

This section specifies the provisions of the Quality Assurance Program.

4.2 Responsibilities

The President approves the Quality Assurance Program and all revisions to it.

The Quality Assurance Manager shall verify that the Quality Assurance Program is properly implemented for all activities that fall within the scope of the program.

4.3 Program Requirements and Attributes

4.3.1 The Quality Assurance Program ensures that activities affecting quality are documented and performed in accordance with written instructions, procedures, or drawings.

4.3.2 The Quality Assurance Program establishes the basic operating policies and specifies the requirements for the procedures to be employed by Graftel. The Quality Assurance Program has been developed to ensure that all quality related work performed by Graftel will be in compliance with the applicable provisions of ISO/IEC 17025-2005, ANSI/NCSL Z540-1-1994 and other specifications which may include 10CFR 50 Appendix B with part 21 applicable only when invoked.

4.3.3 If an outside organization retained by Graftel for safety-related work does not have a Quality Assurance Program, the Graftel Quality Assurance Program may be implemented by prior agreement between both parties. An outside organization's employees working on the project for Graftel shall be trained in the applicable requirements of the program.

In addition, the Quality Assurance Manager of Graftel shall, by prior agreement with the outside organization, have the freedom to verify proper implementation of the Graftel Quality Assurance Program. For certain services provided by companies who do not have a Quality Assurance Program, source evaluation and source inspection may be used to qualify that company as an acceptable vendor to provide safety-related services.

4.4 Preventative Action

Needed improvements and potential sources of nonconformance shall be identified.

4.4.1 If preventative action is required, action plans shall be developed, implemented and monitored

4.4.2 Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.

- 4.4.3 When improvement opportunities are identified, action plans shall be developed, implemented and monitored to take advantage of these opportunities.

4.5 Training

Personnel performing work, which affects activities, determined to be within the scope of the quality assurance program shall be given appropriate training prior to performing those activities.

The training programme shall be relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken shall be evaluated.

- 4.5.1 Personnel performing activities affecting quality shall be qualified and certified. Training shall be provided, as necessary, to ensure that suitable proficiency is achieved and maintained. All such indoctrination and training shall be documented in the personnel files.
- 4.5.2 This training shall include applicable sections of the Quality Assurance Program employed, as well as the technical elements and requirements of the applicable codes and standards.
- 4.5.3 Graftel management shall formulate the goals with respect to the education, training and skills of the personnel performing work that affects quality.
- 4.5.4 Graftel shall have policies and procedures for identifying training needs and providing training of company personnel. The training program shall be relevant to the present and to anticipated future tasks.
- 4.5.5 Graftel shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and calibrations.
- 4.5.6 Graftel management shall authorize specific personnel to perform particular types of sampling, test and/or calibrations, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of lab equipment.
- 4.5.7 Graftel shall maintain records of relevant authorizations, competence, educational and professional qualifications, training, skills and experience of all technical personnel. This information shall be readily available and shall include the data on which authorization and/or competence is confirmed.

4.6 Program Revisions

Requests for revision of the Quality Assurance Program may be made by any employee

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or client of Graftel. The Quality Assurance Manager shall evaluate program revision requests and implement any revisions which he determines to be needed. The President shall review and approve all Quality Assurance Program revisions.

4.7 Control and Issuance of the Quality Assurance Manual

The approved Quality Assurance Manual, and approved revisions, shall be issued as a control document in accordance with the Quality Assurance Program.

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5 DOCUMENT CONTROL

5.1 Purpose

This section specifies the requirements to establish and maintain procedures to control all documents that form part of Graftel's quality system.

5.2 Responsibilities

The Document Control Coordinator shall be responsible for the quality assurance document control system.

5.3 Scope

The document control system shall include both internally and externally generated documents. These may include:

- test and calibration procedures,
- product drawings and specifications
- software, its specifications, documentation and benchmarking,
- the Graftel QA manual
- calculations

5.4 Quality Document Control System

The quality document control system shall be managed in accordance with written procedure(s). Those procedures shall address the distribution of documents, control of documents withdrawn from storage, and the replacement, restoration, or substitution of lost or damaged documents.

- 5.4.1 All documents issued to personnel for use as a part of the quality system shall be reviewed and approved for use by authorized personnel prior to use.
- 5.4.2 Inventory list(s) or the equivalent identifying the revision status, (where applicable), and distribution and/or location of documents included in the program shall be established and readily available.
- 5.4.3 Where applicable, documents shall be periodically reviewed and revised as needed to ensure continuing suitability and compliance with applicable requirements.
- 5.4.4 Invalid or obsolete documents shall be promptly removed from all points of issue or use or otherwise assured against unintended use.
- 5.4.5 Obsolete documents which are retained for either legal or knowledge preservation shall be suitably marked.
- 5.4.6 Quality System document generated by Graftel, shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages, and the issuing authorities.

5.5 Document Changes

Changes to documents shall be reviewed and approved using the same process requirements as used in the original review unless specifically designated otherwise.

- 5.5.1 The personnel making document changes shall have the access to the information required to base their review upon.
- 5.5.2 Where practicable and where this information may be helpful, the altered or added text shall be identified or described in the document in some way.
- 5.5.3 Procedures shall exist to describe how changes in documents maintained in computerized systems are made and controlled.

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6 CONTROL OF RECORDS

6.1 Purpose

This section specifies the requirements for the control of quality records.

6.2 Responsibilities

The Document Control Coordinator shall be responsible for operation of the quality record control system. The Quality Assurance Manager shall be responsible for identifying records related to Quality Assurance Department activities to be included in the record control system.

6.3 Quality Record Control Program

Quality records shall be controlled to ensure that they are correct and available at the location where they are needed.

- 6.3.1 Quality records shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages and the issuing authority.
- 6.3.2 Identification of personnel or organizations responsible for preparing, reviewing, approving, and issuing records
- 6.3.3 Quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable.
- 6.3.4 Quality records shall be stored in a suitable environment to prevent loss or deterioration.
- 6.3.5 Retention times for each type of quality record shall be established.
- 6.3.6 Quality records shall be held secure and in confidence.
- 6.3.7 Procedures shall exist to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of those records.
- 6.3.8 Procedures shall establish current and updated record distribution lists.
- 6.3.9 There shall be control of invalid or obsolete quality records to ensure their prompt removal from all points of use and to prevent their unintended use. Procedures for the control of records and changes shall have provisions to preclude the use of outdated or inappropriate records.
- 6.3.10 There shall be a master list identifying the current revision status of all procedures

- 6.3.11 There shall exist provisions for the revision of obsolete quality records retained for either legal or knowledge preservation purposes. They shall be suitably marked.
- 6.3.12 Procedures shall exist which describe how changes to quality records which are maintained in computerized systems are made and controlled.

6.4 Technical Quality Records

Graftel shall retain records of original observations, derived data and sufficient information to establish an audit trail.

- 6.4.1 Retained records shall include: calibration records, staff records, and a copy of each test report or calibration certificate.
- 6.4.2 The retention time for each of the above types of quality records shall be established.
- 6.4.3 The records for each test or calibration shall contain sufficient information to facilitate if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original.
- 6.4.5 The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.
- 6.4.6 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task. Data recorded by hand may be transcribed to digital format and then discarded following independent verification of correct transcription. The digital data may then be treated as the original observations.
- 6.4.7 When mistakes occur in written records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction.
- 6.4.8 When mistakes occur in electronic records, equivalent measures to those specified in section 6.4.7 shall be taken to avoid the loss or the change of original data.

7 PROCEDURES

7.1 Purpose

Activities affecting quality shall be implemented in accordance with documented procedures. Appropriate quantitative and qualitative criteria shall be included or referenced if needed to ensure that the specified activities have been performed as required.

7.2 Responsibilities

The Manager of Projects & Engineering, or his assignee, determines when standard procedures are needed. He ensures their preparation and approval, and trains personnel in their use.

The Quality Assurance Manager shall be responsible for generating the quality assurance procedures needed to control the activities necessary to verify that applicable activities are performed in accordance with the requirements of the Quality Assurance Program. He also reviews procedures to verify compliance with the Quality Assurance Program and shall be responsible for verifying that activities affecting quality are implemented in accordance with approved and documented procedures.

7.3 Content

Procedures generally will include the following, as applicable:

- Purpose and scope of the document
- Definitions and terms used in the document
- Reference documents or information necessary to perform the activities
- Responsibilities for performing specific activities
- Procedural instructions, step-by-step instructions are only used when required to control attributes such as sequence of operations or specific methodology
- Acceptance criteria, when to verify compliance
- Required interfaces, review, approvals, or actions
- Related or dependent procedures, instructions, or drawings
- Attachments

7.4 Issuance

7.4.1 Procedures shall be prepared, reviewed, and approved prior to the commencement of the activity to be controlled by that procedure.

7.4.2 Revised procedures shall be reviewed and approved at the same level as the original document.

7.4.3 Procedures shall be issued as controlled documents in accordance with this manual.

7.4.4 Historical files of procedures shall be maintained.

8 REVIEW OF REQUESTS, PURCHASE ORDERS AND CONTRACTS

8.1 Purpose

This section establishes review requirements and assigns responsibilities for the control and documentation of requests, purchase orders and contracts.

8.2 Responsibilities

The Manager of Projects & Engineering, or his designee, shall be responsible for the review of customers' technical and quality requirements contained in requests, purchase orders and contracts.

8.3 Program Requirements

8.3.1 Graftel shall establish and maintain policies and procedures for the review of requests, purchase orders and contracts. This review shall also cover any work that is subcontracted.

8.3.2 For testing/calibration work, these policies and procedures shall insure that; requirements and methods used are defined, documented and understood, Graftel has the capability and resources to meet the requirements, the appropriate test and/or calibration method is selected and capable of meeting the clients' requirements.

8.3.3 For the review of routine or simple tasks for which Graftel has past experience successfully performing, the initials and date of the reviewer placed on the client's purchase order are considered adequate.

8.3.4 Any differences between the reviewed customer requirements and Graftel's practices shall be resolved before any work commences.

8.4 Records

Records of reviews, including any significant changes shall be maintained. Records shall also be maintained of pertinent discussions with clients relating to requirements or the results of the work during the period of the execution of the contract.

8.5 Changes

The client shall be informed of any deviation from the contract. If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

8.6 Subcontracting of Tests and Calibrations

When Graftel subcontracts any test or calibration work, the following conditions shall be met.

8.6.1 Graftel shall advise the client in writing that the work has been subcontracted.

8.6.2 Graftel retains ultimate responsibility for the work to the client

- 8.6.3 Graftel shall maintain a list of all authorized subcontractors. All subcontractors shall meet the requirements of ISO 17025-2005. Documented proof of this compliance shall be maintained for each subcontractor on the list.

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9 SERVICE TO THE CLIENT

9.1 Purpose

This section specifies the requirements for service to the client.

9.2 Responsibilities

The Quality Assurance Manager shall be responsible for verifying compliance to all procedures that insure quality service to the client.

9.3 Program Requirements

Graftel should provide reasonable cooperation to clients allowing the monitoring of the laboratories performance of work performed for the client.

- 9.3.1 This cooperation may include providing the client of the client's representative access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the client.
- 9.3.2 Graftel may provide clients with items, records or data needed to verify the quality of specific work performed for that client.
- 9.3.3 Graftel may refuse such monitoring or cooperation at any time to any client. The reasons for this refusal shall be documented, written notification transmitted to the client and a record of the request and refusal stored as a quality record.
- 9.3.4 Graftel shall have procedures in place to ensure the protection of clients' confidential information and proprietary rights.
- 9.3.5 Procedures shall be in place for protecting the electronic storage and transmission of client data and information.

9.4 Customer Complaints

Procedures shall be in place for the resolution of complaints received from clients or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by Graftel.

9.5 Customer Feedback

Graftel shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyses to improve the management system, testing and calibration activities and customer service.

10 PURCHASING SERVICES AND SUPPLIES

10.1 Purpose

This section establishes requirements and assigns responsibilities for the purchasing of services and supplies that may affect the quality of tests, calibrations or products.

10.2 Responsibilities

The Manager of Projects & Engineering, or his designee, shall be responsible for initiating purchase orders, and including technical and quality requirements into the procurement document(s).

The Quality Assurance Manager shall be responsible for verifying the implementation of an effective procurement program. He shall also be responsible for the review and approval of the vendor quality assurance program.

10.3 Program Requirements

- 10.3.1 Procedures shall exist for the selection and purchasing of supplies and services which affect the quality of testing, calibration and of products.
- 10.3.2 Suppliers of critical consumables, supplies and services which affect the quality of testing, calibration and of products shall be evaluated and added to the Authorized Vendors List if approved.
- 10.3.4 The Authorized Vendors List and records of actions taken to check compliance shall be maintained as quality records.
- 10.3.5 Procedures shall exist for the purchase, reception and storage of laboratory reagents, and consumable materials used for tests and calibrations.
- 10.3.6 Procedures shall ensure that purchased supplies, reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. Records of actions taken to check compliance shall be maintained as quality records.
- 10.3.7 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and/or supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.
- 10.3.8 Any procurement document changes shall be subjected to the same degree of control as that utilized in the preparation of the original document.

10.4 Contents of Procurement Documents for Nuclear Safety Related Services or

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Supplies

Procurement documents issued for the procurement of nuclear safety related services or supplies shall include provisions for the following as required:

- Supplier Quality Assurance Program - The quality assurance requirements and the elements of the program applicable to the items, materials, or services procured shall be identified. The vendor's program must comply with 10-CFR 50 Appendix B or Graftel must perform a full audit of the vendor's program to verify compliant with Appendix B requirements.
- Basic Technical Requirements - Drawings, specifications, codes, and industrial standards, with applicable revision data and test and inspection requirements, shall be identified as required.
- Scope of Work - A definition of the scope of work shall be included.
- Right of Access - Permission for authorized representatives of Graftel to have access to the suppliers' (and their suppliers') facilities and records for the purposes of visitation, inspection, surveillance, or quality assurance audits shall be specified.
- Documentation Requirements - Records to be prepared, maintained, or made available for review, such as drawings; specifications; procedures; procurement documents; inspection and test records; personnel and procedure qualifications; and material, chemical, and physical test results shall be identified. Instructions on record retention and disposition shall be provided to vendors.
- Lower Tier Procurement - Applicable requirements of the Graftel Quality Assurance Program and the client's specific quality assurance requirements shall be extended to lower tier suppliers, including purchaser's access to facilities and records.
- Suitability - Suitability of the specified parts, equipment, and/or processes for the application shall be identified.
- Special Instructions - The procurement documents shall clearly identify any applicable special instructions.
- Identification - Provisions for adequate identification of parts, equipment, or supplies shall be specified.
- Handling, Storage, and Shipping - Adequate requirements for handling, storage, cleaning, packaging, and shipping, including handling, storage, and preservation requirements to be maintained upon receipt.
- Provisions for Nonconformance - Methods for handling non-conforming parts, equipment, or processes shall be included.

- 10 CFR Part 21 - Reporting of Defects - The reporting requirements of 10 CFR Part 21 shall be invoked if required.

10.5 Commercial Grade Material

Graftel may purchase material meeting the definition of "Commercial Grade." Dedication of commercial grade items for nuclear safety-related applications may be accomplished by the client, Graftel, or outside sources.

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11 TEST AND CALIBRATION METHODS AND METHOD VALIDATION

11.1 Purpose

This section establishes requirements and assigns responsibilities for test and calibration methods and method validation.

11.2 Responsibilities

The Manager of Projects & Engineering, or his assignee, determines the test and calibration methods and their validation plans.

The Quality Assurance Manager shall be responsible for generating the quality assurance procedures needed to control the activities necessary to verify that applicable activities are performed in accordance with the requirements of the Quality Assurance Program. He also reviews the processes and procedures to verify compliance with the Quality Assurance Program and shall be responsible for verifying that activities affecting quality are implemented in accordance with approved and documented procedures.

11.3 Program Requirements

Graftel, Inc. shall use appropriate methods and procedures for all calibrations, including sampling, handling, transport, storage and preparation of items to be calibrated and where appropriate, the estimation of the measurement uncertainty as well as statistical techniques for analysis of calibration data.

- 11.3.1 Graftel, Inc. has instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for calibration, where the absence of such instructions could jeopardize the calibration results.

All instructions, standards, and manuals are kept up to date and readily available to applicable personnel.

- 11.3.2 Deviations from calibration methods only occur if the deviation has been documented on the calibration report. It must be deemed technically justified and authorized by the Quality Manager and accepted by the client.

- 11.3.3 Graftel, Inc. uses calibration methods, including methods for sampling, which meet the needs of the client and which are appropriate for the calibrations it undertakes. Methods published in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment or based upon well established physical principles are used. Graftel, Inc. uses the latest edition of standards, where possible and appropriate. When necessary, the standard may be supplemented with additional details or improvements.

- 11.3.4 Graftel-developed methods or methods adopted by Graftel can be used if deemed appropriate and validated.
- 11.3.5 The client is informed as to the method chosen by listing the method on the calibration certificate or test report. The client is informed when the method proposed by the client is considered inappropriate or out of date.
- 11.3.6 Introduction of calibration methods developed by the laboratory for its own use is a planned activity by technically qualified personnel equipped with adequate resources. If plans for development of methods should change, all personnel involved will be immediately informed of the changes. Only the most recent revision of internally developed methods will be available.
- 11.3.7 When it is necessary to use methods not covered by standard methods, (special processes) they are subject to agreement with the client and include a clear specification of the client's requirements and the purpose of the calibration. The method is validated appropriately before use.
- 11.3.8 Graftel, Inc. validates non-standard methods, standard methods used outside their intended range and amplification of standard methods to confirm that the methods are fit for the intended use. The validation is as extensive as necessary to meet the needs of the given application or field of application. Graftel, Inc. records the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.
- 11.3.9 The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object) as assessed for the intended use are relevant to the clients needs.
- 11.3.10 Graftel, Inc. has a procedure to calculate its estimation of the uncertainty of measurement. These calculations are available for specified ranges and for all quantities/measurements in its scope.
- 11.3.11 Graftel shall have and shall apply procedures for estimating uncertainty of measurement. In cases where this estimation is not practical, a reasonable estimation shall be made.
- 11.3.12 When estimating the uncertainty of measurement, all uncertainty components are taken into account, and combined using the basic concepts as described in the GUM (Guide to the Expression of Uncertainty in Measurement). Approved software may be used to

facilitate this process

11.3.13 Calculations and data transfers are subject to appropriate checks in a systematic manner.

11.3.14 Where computers or automated equipment is used for the acquisition, processing, recording, reporting, storage or retrieval of calibration data, Graftel, Inc. ensures that:

- Computer software developed by Graftel, Inc. is documented in sufficient detail and suitable validated or otherwise checked as being adequate for use.
- Procedures and/or policies are established and implemented for protecting the integrity of the data.
- Computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of calibration data.

12 CONTROL OF PURCHASED ITEMS AND SERVICES

12.1 Purpose

This section specifies the requirements for the procurement of items and services which may affect quality.

12.2 Responsibilities

The Manager of Project and Engineering or his designee shall be responsible for establishing requirements for the procurement of items and services which may affect quality.

The Quality Assurance Manager shall be responsible for verifying the implementation of those requirements.

12.3 Program Requirements

A program shall be established and documented to ensure that purchased items and services, whether purchased directly or through subcontractors, conform to specified requirements.

The procurement program shall include provisions for:

- Source evaluation and selection
- Source inspection, audit, and examination of items or services upon delivery or completion
- Evaluation of objective evidence of quality furnished by the supplier

Evaluation of the effectiveness of the control of quality by contractors and subcontractors shall be assessed at intervals consistent with the importance, complexity, and quantity of the product or services.

13 ITEM CONTROL AND IDENTIFICATION

13.1 Purpose

This section specifies requirements for item control and identification.

13.2 Responsibilities

The Manager of Projects & Engineering shall be responsible for developing and implementing a program for the control and identification of items which may affect quality.

The Quality Assurance Manager shall be responsible for verifying the implementation of this program.

13.3 Identification

Identification of items shall be accomplished by marking or tagging whenever possible. When this is impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed. Identification may be either on the item or on records traceable to the item. When identification marking is used, the marking shall be clear, unambiguous, and applied in such a manner as not to affect the function of the item.

When items are subdivided, markings shall be transferred to each part of the item and shall not be obliterated or hidden by surface treatments or coatings unless other means are substituted.

13.4 Program Requirements

The program shall ensure that items which may affect quality are properly identified and controlled. The program shall ensure that only correct and accepted items are used, shipped or calibrated.

13.5 Traceability

When required by codes, standards, or specifications, the program shall provide traceability of parts, or components to specific documentation such as drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports, and calibration reports, as applicable.

14 TEST AND MEASURING EQUIPMENT

14.1 Purpose

This section specifies requirements for test and measuring equipment.

14.2 Responsibilities

The Manager of Projects & Engineering shall be responsible for developing and implementing an effective control program for test and measuring equipment.

The Quality Assurance Manager shall be responsible for verifying the implementation of that program. He shall also make the final determinations as to which devices need to be included in the program.

14.3 Program Requirements

14.3.1 Graftel, Inc. is furnished with all items of sampling, measurement and test equipment required for the correct performance of the calibrations it performs, including sampling, preparation of calibration items, processing and analysis of calibration data, as applicable. In cases where the laboratory needs to use equipment outside its permanent control, it ensures that the requirements of this manual are met.

14.3.2 Equipment and its software used for calibration and sampling is capable of achieving the accuracy required and complies with specifications relevant to the calibrations concerned. Calibration programs are established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment, including that used for sampling, is checked to establish that it meets the laboratories specification requirements, complies with the relevant standard specifications, and is checked and/or calibrated before use.

14.3.3 Equipment is operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment are readily available for use by the appropriate laboratory personnel.

14.3.4 Each item of equipment and its software used for calibration and significant to the results is, when practical, uniquely identified.

14.3.5 Records are maintained of each item of equipment, and its software used to perform calibrations in the laboratory. Each item of equipment has an information folder of some form which includes the following information:

- a) the identity of the item of equipment and its software (usually as header information on calibration certificates for the asset, item e);

- b) the manufacturer's name, type identification, and serial number or other unique identification;
 - c) see item e);
 - d) the current location, where appropriate;
 - e) the manufacturers model number indicates the location, in a separate file, of any operation or service manuals available for the item;
 - f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
 - g) the maintenance plan, where appropriate, and maintenance carried out to date;
 - h) any damage, malfunction, modification or repair to the equipment.
- 14.3.6 Graftel, Inc. has policies and/or procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.
- 14.3.7 Equipment that has been subjected to overloading or mishandling, or gives suspect results, or has been shown to be defective or outside specified limits, is taken out of service, clearly labeled or marked, and appropriately stored until it has been repaired and shown by calibration or test to perform correctly. Management examines the effect of the defect or departure from specified limits on previous calibrations and institutes a Control of Non-Conforming Work procedure or its equivalent.
- 14.3.8 Whenever practicable, all equipment under the control of the laboratory is labeled, coded or otherwise identified to indicate the status of calibration including the date when last calibrated and the date of expiration criteria when recalibration is due.
- 14.3.9 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory insures that the function and calibration status of the equipment is checked and shown to be satisfactory before the equipment is returned to service.

- 14.3.10 When checks are needed to maintain confidence in the calibration status of equipment, these checks are carried out periodically according to a defined procedure.
- 14.3.11 Where calibrations give rise to a set of correction factors, the laboratory has procedures or policies to ensure that any copies are correctly updated.
- 14.3.12 Calibration equipment, including both hardware and software is safeguarded from adjustments which would invalidate the calibration results.

14.4 Measurement Traceability

All equipment used for calibrations, including equipment for subsidiary measurements having a significant effect on the accuracy or validity of the result of the calibration or sampling is calibrated before being put into service. Graftel has an established program for the calibration of its equipment.

- 14.4.1 Graftel's program for calibration of its equipment is designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI).

The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute.

Traceability of measurement is assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability to SI units.

The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

- 14.4.2 For calibrations that cannot strictly be made in SI units, calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:
- 14.4.2.1 The use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;

- 14.4.2.2 The use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.
- 14.4.3 Participation in a suitable program of inter-laboratory comparisons is required where possible.
- 14.4.4 Reference standards used by Graftel shall be calibrated by a body that can provide traceability. Reference standards of measurement are used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards are calibrated before and after any adjustment to the standard.
- 14.4.5 Reference materials are, where possible, traceable to SI units of measurement, or to certified reference materials. Internal reference materials are checked as far as is technically and economically practical.
- 14.4.6 Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials are carried out according to defined procedures and schedules.
- 14.4.7 Graftel, Inc. has procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity, where the absence of such could jeopardize the quality in calibration results.

14.5 Calibration Intervals and Methods

Calibration methods and intervals for each item shall be defined and based on the type of equipment, its use, manufacturer's recommendations, stability characteristics and history, required accuracy, and other relevant conditions.

When there is reason to believe that a calibrated device may not be in current calibration, a special calibration shall be performed.

14.6 Out of Calibration Equipment

When test and measurement equipment is found to be lost, malfunctioning, or out of calibration, an evaluation shall be performed and documented. This evaluation shall address the validity of measurements made using that equipment since it's last calibration, and their acceptability. The documented results of the evaluation of the validity of previous inspection and/or test results shall be evaluated and approved by the Quality Assurance Manager.

Test and measurement equipment, which is found out of calibration, shall be tagged as such and repaired or replaced as required.

14.7 Handling and Storage

Measurement and test equipment that is susceptible to loss of accuracy due to improper handling, storage, or changes in ambient environmental conditions shall be identified by the M&TE Manager.

The M&TE Manager shall also identify any special precautions, which need to be taken to ensure the required accuracy of the measurement and test equipment.

14.8 Calibration Records

Records shall be maintained and equipment suitably marked to indicate calibration status and to permit traceability to the instrument's calibration records.

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15 NON-CONFORMING ITEMS, SERVICES AND ACTIVITIES

15.1 Purpose

This section specifies the requirements for the control of non-conforming items, services, and activities.

15.2 Responsibilities

Any Graftel personnel discovering a non-conforming condition are responsible for reporting this condition to the Quality Assurance Manager.

The Quality Assurance Manager shall be responsible for implementing and monitoring the nonconformance program.

15.3 Program Requirements

This program shall control items, services, or activities, which do not conform to applicable requirements of Graftel or agreed upon requirements from the client.

- 15.3.1 The program shall include, as applicable, written procedures for identification, documentation, segregation, disposition, and notification to affected organizations.
- 15.3.2 Activities which have been determined to be nonconforming shall be halted and any reports or calibration certificated based upon those activities shall be withheld.
- 15.3.3 An evaluation of the significance of the nonconforming work shall be performed.
- 15.3.4 Based upon the evaluation, the required corrective actions shall be taken. This may include client notification and the recall of work performed.
- 15.3.5 Criteria for the resumption of work shall be proceduralized.
- 15.3.6 Where the evaluation indicates the potential for reoccurrence of the nonconformance, corrective action shall be taken as discussed in section 22 of this manual.

15.4 Identification and Segregation of Non-Conforming Items

Non-conforming items shall be marked or tagged and controlled by physical segregation. Where physical segregation is not practical, non-conforming items may be only marked or tagged.

15.5 Disposition of Non-Conforming Items, Services, or Activities

The program shall control further use, delivery, or installation of a non-conforming or defective item pending a decision on its disposition. Non-conforming items may be disposed of by evaluation and accepting as is, rejecting, or repairing the defective item. Following repair, the item shall be re-tested.

Documentation shall be required to verify the acceptability of non-conforming items dispositioned as repair, rework, retest, or used as is.

15.6 Trends

The Quality Assurance Manager shall retain copies of closed Non-conformance reports for analysis of possible trends.

The President and the Manager of Projects & Engineering shall periodically review these non-conformance reports for trends, and take applicable actions as required.

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16 CALIBRATION and TEST CONTROL

16.1 Purpose

This section specifies requirements for the control of all calibration and testing activities that affect quality.

16.2 Responsibilities

- 16.2.1 The Manager of Projects & Engineering shall develop and implement a calibration and test control program.
- 16.2.2 The Quality Assurance Manager shall verify the implementation of that program.

16.3 Calibrations and Test Control Program Requirements

Calibrations and tests which are required to verify the conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service shall be planned and executed using written procedures. This includes instrument calibrations.

- 16.3.1 The characteristics to be calibrated or tested and the calibration and test methods to be employed shall be specified.
- 16.3.2 Calibration and test results shall be documented and their conformance with acceptance criteria shall be evaluated.
- 16.3.3 Calibrations and tests required to collect data, shall be planned, executed, documented, and evaluated.
- 16.3.4 The organization or responsible for the design of the item being tested or their representative shall provide the test requirements and acceptance criteria, unless designated otherwise by the item's owner. When this information is not available, the project engineer shall provide the test requirements and acceptance criteria.

16.4 Sampling

Graftel has a sampling plan/procedure for sampling when it carries out sampling of substances, materials or products.

- 16.4.1 All sampling plans shall be based upon the appropriate statistical methods. They shall also address the factors to be controlled to ensure the validity of the test and calibration results.
- 16.4.2 Where the client required deviations, additions or exclusions from the documented sampling procedure, these deviations shall be shall be recorded in detail.
- 16.4.3 Graftel has procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken.

16.5 Calibration and Test Procedures

Calibration and test procedures shall include the following, as applicable:

- Calibration or test objectives
- Provisions for assuring that the established prerequisites have been met
- Required inspection witnesses and hold points, (only if applicable)
- Required equipment and instrumentation
- Required environmental conditions, (if any)
- Condition of the item to be calibrated or tested
- Provisions for data acquisition.

16.6 Accommodations and Environmental Conditions

- 16.6.1 Facilities used for tests/calibration shall have environmental conditions that facilitate the performance of the tests and/or calibrations.
- 16.6.2 Graftel shall monitor, control and record environmental conditions when required or where they may have a significant influence on the quality of test or calibration results. Tests or calibrations shall be stopped when the environmental conditions may jeopardize the results of the tests or calibrations.
- 16.6.3 There shall be effective separation between neighboring areas in which there are incompatible activities. As required, measures shall be taken to prevent cross contamination between these areas.
- 16.6.4 Access to and use of areas affecting quality is restricted to authorized personnel. Unauthorized personnel can access these areas only under the control of authorized personnel. The degree of control required shall be determined on a case by case basis.
- 16.6.5 Good housekeeping shall be maintained in the laboratory. General housekeeping procedure(s) shall exist. Special procedures are prepared where necessary.

16.7 Calibration and Test Results

Graftel, Inc. has quality control procedures for monitoring the validity of tests and calibrations undertaken.

- 16.7.1 Calibration and test data is recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results.
- 16.7.2 The quality of calibration is ensured by monitoring the calibration results. This monitoring may be performed by performing periodic spot checks of the calibration standard systems by using reference materials or other standards.

- 16.7.3 Spot checks may alternately be performed by participation in inter-laboratory comparisons of the devices calibrated.
- 16.7.4 Spot checks may alternately be performed by recalibration of reference standard systems using the same or different methods.
- 16.7.5 Calibration and test data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.

16.8 Reporting of Test and Calibration Results

The results of each calibration, or series of calibrations carried out by Graftel, Inc. are reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the calibration methods.

The results are reported in a calibration report and include all information requested by the client and necessary for the interpretation of the calibration results and all information required by the method used.

- 16.8.1 Unless there exists exceptional reasons for not doing so, each calibration certificate will include at least the below information.
- a) a title (e.g. Certificate of Calibration)
 - b) name and address of laboratory, and location where the calibrations were carried out if different from the address of the laboratory;
 - c) unique identification of the calibration certificate and on each page an identification in order to ensure that the page is recognized as a part of the calibration certificate. A clear identification of the end of the calibration certificate;
 - d) name and address of the client placing the order;
 - e) identification of the method used;
 - f) a description of, the condition of, and unambiguous identification of the item(s) calibrated;
 - g) the date of receipt of the calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the calibration;
 - h) reference to sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;
 - i) the calibration results with, where appropriate, the units of measurement;
 - j) the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the calibration certificate;
 - k) where relevant, a statement to the effect that the results relate only to the items calibrated.

Any of the above information which is not reported to the client is readily available in the laboratory.

- 16.8.2 In addition to the requirements listed in section 16.8.1, test reports shall, when necessary for the interpretation of the test results are required to include the below items.
- a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions.
 - b) where relevant, a statement of compliance or non-compliance with requirements and/or specifications.
 - c) where applicable, a statement on the estimated uncertainty of measured
 - d) where appropriate and needed, opinions and interpretations
 - e) required additional information

Any of the above information which is not reported to the client is readily available in the laboratory.

- 16.8.3 For test reports containing the results of sampling, the requirements listed in sections 16.8.1 and 16.8.2 as well as the information listed below shall be included when required for the interpretation of the test results.
- a) the date of sampling
 - b) unambiguous identification of items being sampled
 - c) the location of sampling
 - d) a reference to the sampling plan and procedures used
 - e) environmental conditions during the sampling that may effect the interpretation of results
 - f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specifications concerned.

- 16.8.4 In addition to the information listed in 16.8.1, where necessary for the interpretation of results, calibration certificates shall include the following:
- a) the environmental conditions under which the calibration was made that have an influence on the measurement results;
 - b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;
 - c) evidence that the measurements are traceable.

- 16.8.5 The calibration certificate relates only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this statement identifies which clauses of the specification are met or not met.

- 16.8.6 When a statement of compliance with a specification is made omitting the measurement results, Graftel shall record those results and maintains them for possible future reference.
- 16.8.7 When statements of compliance are made, the uncertainty of measurement is taken into account.
- 16.8.8 When an instrument for calibration has been adjusted or repaired, the calibration results before adjustment or repair, if available are reported.
- 16.8.9 The calibration certificate does not contain any recommendation on the recalibration interval except where this has been agreed upon with the client. This requirement may be superseded by legal regulations.

16.9 Opinions and Interpretations

When opinions and interpretations are included, the laboratory documents the basis upon which the opinions and interpretations are made. Opinions and interpretations are clearly marked as such in a test report.

16.10 Calibration Results Obtained from Subcontractors

In the event that a calibration is subcontracted, the client must approve the subcontracting either in writing or verbally, this approval is documented. The subcontracted laboratory performing the work issues the calibration certificate to the contractor. Graftel, Inc. may issue a certificate as the contractor, clearly identifying the subcontractor and includes the certificate provided by the subcontractor to the client.

16.11 Electronic Transmission of Results

In the event that calibration results are transmitted by telephone, fax, e-mail, or other electronic or electromagnetic means, the customer must approve the process prior to occurrence.

16.12 Format of Certificate

The format utilized by Graftel, Inc. is designed to accommodate each type of calibration carried out and to minimize the possibility of misunderstanding or misuse.

Attention is given to the layout of the calibration certificate, especially with regard to the presentation of the calibration data and ease of assimilation by the reader.

Headings are standardized as far as possible.

16.13 Amendments to Calibration Certificates

Material amendments to a calibration certificate after issue are made in the form of a further document, or data transfer, which includes the statement "Supplement to Calibration Certificate, certificate number, (or as otherwise identified) or an equivalent form of wording. Such amendments must meet the requirements of International

Standards referenced by Graftel, Inc. as being in compliance to.

When it is necessary to issue a complete new calibration certificate, it is uniquely identified and contains a reference to the original that it replaces. The new certificate is issued as a revision to the original certificate.

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17 HANDLING, STORAGE, AND SHIPPING

17.1 Purpose

This section specifies the requirements for handling, storage, and shipping of components, items, and systems which may affect quality.

17.2 Responsibilities

The Manager of Projects & Engineering shall develop and implement an effective control program for the handling, storage, and shipping of components, items, and systems which may affect quality.

The Quality Assurance Manager shall verify the implementation this program. He shall also determine which components, items and systems the requirements contained in this section must be applied to.

17.3 Requirements

The program shall include provisions for the handling, storage, cleaning, packaging, and shipping of the included items in accordance with established procedures to prevent damage or loss and to minimize deterioration.

17.4 Marking and Labeling

- 17.4.1 Graftel reference standards' markings and labeling shall be adequate to identify, maintain and preserve the standards.
- 17.4.2 Client equipment at the Graftel laboratories shall be assigned a unique ID number upon receipt. This number shall be marked or labeled on the equipment in a way that it may be removed prior to shipping.

17.5 Handling of Calibration Items

The requirements of this quality system are met pertaining to the transportation, receipt, handling, protection, retention, and/or disposal of calibration items. It includes provisions necessary to protect the integrity of the calibration item.

- 17.5.1 Upon receipt of an item for calibration, either in the lab or in the field, an inspection is performed identifying any abnormalities or departures from normal or specified conditions, as may be described in the relevant calibration method and is recorded. When there is any doubt as to the suitability of an item for calibration, or when an item does not conform to the description provided, or the calibration required is not specified in sufficient detail, the laboratory consults the client for further instructions before proceeding and records the conclusion of the discussion.
- 17.5.2 Calibration item(s) prepared, handled, stored and/or transported by Graftel, Inc. are dealt with in an appropriate manner that ensures the avoidance of deterioration, loss or damage. These instructions are

provided as necessary either in writing or verbally, this includes any instructions provided with the item. When item(s) are to be stored under specified environmental conditions, these conditions are maintained, monitored and recorded.

- 17.5.3 Where calibration item(s) or portion of an item is to be held secure, the laboratory provides storage and security that protect the condition and integrity of the secured item(s) or portions concerned.
- 17.5.4 Delivery of calibrated item(s) to the customer is done with care to ensure that the item(s) are not subjected to stress that could corrupt the item's integrity.
- 17.5.5 Measurement standards transported for in-field calibration of clients' equipment are transported with care to prevent stress response error.

18 AUDITS

18.1 Purpose

This section provides a comprehensive system of planned and periodic audits to verify compliance and effectiveness of the Quality Assurance Program. The requirements of this section apply to both internal and external audits performed by or on an organization participating in any activities affecting quality.

18.2 Responsibilities

The Quality Assurance Manager develops and implements the quality audit program.

The recipient of an audit report shall be responsible for reviewing the audit report, identifying the cause of reported deficiencies, and will implement corrective action to correct the deficiency in order to preclude repetition.

18.3 Audit Program Requirements

- 18.3.1 A written audit plan and checklist shall be prepared before each audit. The report from a similar completed audit may be used in place of the plan and checklist.
- 18.3.3 Appropriately trained personnel not having direct responsibilities in the areas being audited shall perform the audits in accordance with the written audit plan and checklist. This requirement does not apply to the annual Graftel, Inc. internal audit.
- 18.3.4 The auditing personnel shall document the audit results and shall review the documented audit results with management directly responsible.
- 18.3.5 Responsible management shall take necessary action to correct the deficiencies revealed by the audit.
- 18.3.6 Audits shall be performed:
- To provide an objective evaluation of compliance with established requirements, methods, and procedures
 - To determine adequacy of Quality Assurance Program performance
 - To verify implementation of recommended corrective action
- 18.3.7 The audit shall include an evaluation of quality assurance practices, procedures, and instructions, the effectiveness of implementation and conformance with policy directives. This evaluation shall include work areas, activities, processes, and items, and review of documents and records.
- 18.3.8 Deficient areas shall be reviewed until corrections have been accomplished.

18.3.9 Audit records shall be maintained in accordance with this manual.

18.4 Personnel

Audit personnel shall be selected and assigned who are independent of any direct responsibilities for any activities they will audit. Persons responsible for the activities being audited shall not be involved in the selection of the audit team. This requirement does not apply to the annual Graftel, Inc. internal audit.

Audit personnel selected for quality assurance auditing assignments shall have experience and/or training commensurate with the scope, complexity, or special nature of the activities to be audited. Audit personnel shall be trained and qualified.

A lead auditor shall be assigned to each auditing team to organize, direct, and report audit findings and to evaluate corrective action. An auditing team of one person must be a lead auditor.

Auditor training records shall be maintained in the auditors' personnel files..

18.5 Internal Audits

An internal audit of Graftel, Inc. shall be performed annually in accordance with an internal audit procedure. The objective of the audit is to verify that Graftel operations comply with the requirements of its quality program.

- 18.5.1 The internal audit shall address all elements of the Graftel quality system including is testing and/or calibration activities.
- 18.5.2 It is the responsibility of the quality manager to plan and organize internal audits.
- 18.5.3 Internal audits shall be carried out by trained and qualified personnel. These personnel shall be as independent as practical from the activities being examined when permitted by the resources available at the time of the audit.
- 18.5.4 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of Graftel's test or calibration results, Graftel shall take timely corrective actions.
- 18.5.5 When audit findings cast significant doubt on the effectiveness of the operations or on the correctness or validity of Graftel's test or calibration results, Graftel shall notify clients in writing if investigations show that results sent to them by Graftel were materially affected in a negative manor.
- 18.5.6 The audit findings and corrective actions that arise from them shall be recorded.
- 18.5.7 Follow-up audit activities shall verify and record the implementation

and effectiveness of the corrective actions.

18.6 Management Reviews

In accordance with internal procedure(s), Graftel's management shall annually conduct a review of the quality system, testing and/or calibration activities to ensure their continuing suitability and effectiveness and to introduce necessary changes or improvements. This review shall include recommendations for improvement.

Overall objectives shall be established, and shall be reviewed during the management review.

- 18.6.1 The review shall take the below factors into account.
- The suitability of policies and procedures
 - Reports from management and supervisory personnel
 - The outcome of recent internal audits
 - Corrective and preventative actions taken
 - Assessments performed by external bodies
 - Results of interlaboratory comparisons or proficiency tests
 - Changes in the volume and type of work being performed
 - Client feedback and complaints
 - Other relevant factors such as quality control activities, resources and staff training
- 18.6.2 Findings from management reviews and the actions that arise from them shall be recorded.
- 18.6.3 Graftel management shall ensure that the actions required are carried out within an appropriate and agreed upon timescale.

18.7 Audit Reports

The lead auditor shall document the audit and sign the audit report. The audit report shall contain sufficient information to be a stand-alone document. The Quality Assurance Manager shall approve the audit report.

The lead auditor shall evaluate the audit response, verify its implementation, and accept it or request further corrective action.

The Manager of Projects and Engineering or his designee shall review audit results.

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19 INSPECTION

19.1 Purpose

This section establishes requirements and assigns responsibilities for planning and performing inspections of items and activities affecting quality to verify conformance to specified requirements.

19.2 Responsibilities

The Manager of Projects & Engineering shall develop and implement an effective inspection program.

The Quality Assurance Manager shall verify the implementation of an effective inspection program.

19.3 Inspection Program Requirements

The program for inspection of items or activities affecting quality shall verify conformance with documented procedures or drawings.

Characteristics to be inspected and inspection methods to be employed shall be specified, and inspection results shall be documented.

Inspection for acceptance shall be performed by persons other than those who performed or directly supervised the work being inspected. Each person who performs inspection for acceptance shall be qualified to perform the assigned inspection tasks.

If mandatory inspection hold points are required, the specific hold points shall be indicated in appropriate documents. Work shall not proceed without the consent of the person who assigned the hold point, or a designated representative. Such consent shall be documented prior to continuation of work beyond the designated hold point.

Inspection of items in process shall be performed where necessary to verify quality for work activities. If inspection of processed items is impossible or disadvantageous, indirect control through monitoring methods, equipment, and personnel shall be provided.

Final inspections shall include a records review of results and resolution of any nonconformances identified by prior inspections. The final inspection shall document a conclusion regarding conformance of the item to specified requirements.

20 INSPECTION AND TEST PERFORMANCE STATUS

20.1 Purpose

This section establishes requirements and assigns responsibilities for ensuring identification of inspection and test status.

20.2 Responsibilities

The Manager of Projects & Engineering shall develop and implement an effective program for identifying inspection and test status.

The Quality Assurance Manager shall verify the implementation of an effective program to ensure identification of inspection and test status.

20.3 Program Requirements

The program shall provide means for ensuring that required inspections and tests are performed and that the acceptability of items with regard to inspections and tests performed is readily apparent. Nonconforming items shall be clearly identified.

20.4 Inspection and Test Status

Status indicators, such as physical location, tags, markings, routing sheets, stamps, or inspection records, shall be used to maintain inspection and test status. The program shall provide for ensuring that test specimens have passed the required inspections and tests. Written procedures shall include provisions for the authority for application and removal of tags, markings, labels, and stamps.

21 REPORTING OF DEFECTS AND NONCOMPLIANCE PER 10 CFR PART 21

21.1 Purpose

This section establishes the responsibilities for compliance with the requirements of Nuclear Regulatory Commission (NRC) regulation 10 CFR Part 21 "Reporting of Defects and Noncompliance."

21.2 Definitions

Definitions of terminology used in 10 CFR Part 21 are provided in Quality Assurance Procedures. For the purposes of this section, the following definitions of terms used within Graftel shall apply:

- Client - A buyer of Graftel's services.
- Potential Deficiency - A condition which raises a question as to the existence of a defect or the violation of a regulatory requirement.
- Project Manager - Technical and/or project manager responsible for technical or managerial activities and performance of Graftel's employees, contractors, or consultants on a client contract.

21.3 Responsibilities

- 21.3.1 The President is responsible for notifying the client and/or the NRC, as appropriate, of a potential deficiency or nonconformance. In the absence of the President, his designee shall be responsible for notifying the client and/or NRC, as appropriate, of a potential deficiency or non-conformance.
- 21.3.2 Each employee of Graftel is responsible for notifying the Manager of Projects and Engineering and the Quality Assurance Manager of conditions which the employee perceives as potential deficiencies or noncompliances identified by 10 CFR Part 21.
- 21.3.3 The Manager of Projects and Engineering and the Quality Assurance Manager are responsible for evaluating potential deficiencies and non-conformances reported to them. If they agree that a condition is potentially reportable, they are responsible for notifying the President or his designee within three working days.
- 21.3.4 The Manager of Projects & Engineering is responsible for handling appeals of decisions against reportability of a condition.
- 21.3.5 The Quality Assurance Manager is responsible for the posting requirements specified in subsection 21.4. In the absence the President, his designee shall assume responsibility for notifying the client and/or the NRC, as appropriate, of a potential deficiency or nonconformance.

21.4 Posting

The Quality Assurance Manager is responsible for posting in a conspicuous location(s) Section 206 of the Energy Reorganization Act of 1974; 10 CFR Part 21; and a notice which describes the regulations and procedures, indicates where they may be examined, and states the name of the individual to who reports may be made.

21.5 Evaluation of Potential Deficiencies and Non-Conformances

- 21.5.1 The identification and reporting of potential deficiencies and noncompliances are initiated when an employee finds a condition that he or she believes is a noncompliance or deficiency defined in Section 206 of the Energy Reorganization Act of 1974 or 10 CFR Part 21.
- 21.5.2 The employee shall notify the Manager of Projects and Engineering and the Quality Assurance Manager of a potential deficiency or nonconformance and shall provide adequate documentation to support a technical decision. If the initial notification is oral, a written description of the potential deficiency or nonconformance shall be provided promptly.
- 21.5.2.1 The President or his designee shall notify the client that a potential deficiency or non-conformance is being evaluated within two working days.
- 21.5.2.2 The Manager of Projects and Engineering and the Quality Assurance Manager shall inform the President of a potential deficiency or nonconformance within three working days.
- 21.5.3 The Manager of Projects and Engineering and the Quality Assurance Manager shall evaluate the identified potential deficiency or nonconformance as soon as practicable, for reportability to the NRC, to determine if it could create a substantial safety hazard were it to remain uncorrected. This evaluation shall be completed within 60 days of discovery, except as provided in section 21.5.4 below.
- 21.5.4 The Manager of Projects and Engineering and the Quality Assurance Manager shall ensure, that if the evaluation of the identified potential deficiency or nonconformance cannot be completed within 60 days of discovery, an interim report is prepared and submitted to the NRC through the President or his designee. The interim report should describe the deficiency or nonconformance that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the potential deficiency or nonconformance.
- 21.5.5 The Manager of Projects and Engineering and the Quality Assurance Manager shall ensure that the President or his designee is informed as soon as practicable, and, in all cases, within five working days after the completion of the evaluation described in subsections 21.5.3

and 21.5.4, if the construction or operation of a facility or activity, or a basic component supplied for such facility or activity either (a) fails to comply with the Energy Reorganization Act of 2174, as amended, or any applicable rule, regulation, order, or license of the NRC relating to a substantial safety hazard, or (b) contains a defect.

- 21.5.6 If the Manager of Projects and Engineering and the Quality Assurance Manager determine that Graftel does not have the capability to perform the evaluation to determine if a defect exists, the President or his designee must inform the client within five working days of this determination so that the client may evaluate the deviation or failure to comply pursuant to 10 CFR Part 21, Section 21.21 (a). The client should notify Graftel of the action it has taken concerning the potentially reportable condition.
- 21.5.7 The President (or, in his absence, the Manager of Projects & Engineering or the Quality Assurance Manager) must notify the NRC when he obtains information which reasonably indicates a deficiency or nonconformance that is reportable.
- 21.5.8 If at any stage during the evaluation process it is determined that the evidence does not support reportability, the employee (or member of management who had identified the potentially reportable item) shall be notified. If the employee (or member of management) does not agree, he shall follow the appeals procedure described in subsection 21.6 of this section.
- 21.5.9 If Graftel, as a corporate entity, disagrees with a client's determination that a potentially reportable defect or noncompliance is not reportable, the President of Graftel or his designee shall be responsible for reporting such potential defect or non-compliance to the NRC directly, in accordance with subsection 21.8 of this section. The client shall be notified of the decision to report the condition before Graftel notifies the NRC.

21.6 Appeals Procedure

- 21.6.1 The employee shall provide the Manager of Projects & Engineering, with the documented evidence of a potential deficiency or non-conformance.
- 21.6.2 If the Manager of Projects & Engineering does not concur with the employee that a potentially reportable deficiency or non-compliance exists, he shall notify the employee that the potentially reportable condition was determined to not be reportable with an explanation of the reasons for this decision.
- 21.6.3 If the employee is not satisfied with the results of the initial appeal, he may pursue the final appeals procedure of subsection 21.7 below.

21.7 Final Appeals Procedure

- 21.7.1 The final appeals procedure shall be used only as a last resort if the employee (or member of management) is not satisfied with the results of the initial appeal (subsection 21.6).
- 21.7.2 The employee shall advise the Manager of Projects & Engineering, that he intends to provide the NRC with evidence of the potential deficiency.
- 21.7.3 Within one working day, the Manager of Projects & Engineering shall inform the Project Manager, Quality Assurance Manager, and President of the employee's intent to notify the NRC.
- 21.7.4 The President or his designee shall notify the client organization within one working day that the employee intends to provide evidence of a potential defect to the NRC.

21.8 Notification to the NRC

- 21.8.1 The notification to the NRC of a failure to comply or of a defect under this section is not required if the President has actual knowledge that the NRC has been notified in writing of the defect or the failure to comply.
- 21.8.2 Notification to the NRC required by this section shall be made as follows:
- 21.8.2.1 Initial notification should be by facsimile (FAX), which is the preferred method of notification, to the NRC Operations Center at 301/816-5151 or by telephone at 301/816-5100 within two days following receipt of information by the President (or, in his absence, the Manager of Projects & Engineering or the Quality Assurance Manager) on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in subsection 21.5.4.
- 21.8.2.2 Written notification shall be made within 30 days to the NRC at the following address:
Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555
- 21.8.2.3 In the case of a licensee, a copy must also be sent to the Regional Administrator
- 21.8.3 The President shall forward to the affected client a copy of any notification or report sent to the NRC by Graftel.

21.9 Correction Action

The Quality Assurance Manager shall issue a Non-conformance and Corrective Action Plan (NCR) for any condition that is evaluated under this section and does not comply with the quality requirements of the Graftel Quality Assurance Manual. The NCR shall be issued, corrective action taken, and the NCR closed out in accordance with this manual.

21.10 Maintenance and Inspection of Records

- 21.10.1 Graftel shall prepare and maintain records necessary to accomplish the purposes of 10 CFR Part 21. Such records shall be maintained in accordance with this manual.
- 21.10.2 Graftel shall retain evaluations of all deviations and failures to comply for a minimum of five years after the date of the evaluation.
- 21.10.3 Graftel shall retain any notifications sent to clients for a minimum of five years after the date of the notification.
- 21.10.4 Graftel shall retain a record of clients to whom they have provided services associated with basic component or engineering services for 10 years after delivery of such services.
- 21.10.5 Graftel shall provide the NRC, at all reasonable times, the opportunity to inspect records pertaining to basic components, or engineering services, that relate to the discovery, evaluation, and reporting of deviations, failures to comply and defects, including any advice given to purchasers of licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a basic component.

22 CORRECTIVE ACTIONS

22.1 Purpose

This section addresses those aspects of the Quality Assurance Program concerned with the identification, reporting, and correction of conditions adverse to quality performance and compliance.

This section does not address safety-related defects reporting per 10 CFR Part 21. Refer to Section 21 of this manual for 10 CFR Part 21 requirements.

22.2 Responsibilities

The Manager of Projects & Engineering develops and implements an effective corrective action program.

The Quality Assurance Manager evaluates each deficiency to determine whether or not it is a significant condition adverse to quality. He also evaluates the effectiveness of corrective action and verifies its implementation.

The President is responsible for reporting significant conditions adverse to quality to the client in accordance with the requirements specified in this manual.

22.3 Corrective Action Program Requirements

- 22.3.1 Procedures shall ensure that conditions adverse to quality such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified, documented, reported to appropriate levels of management, and corrected.
- 22.3.2 The root cause of the identified problem shall be investigated.
- 22.3.3 Each condition adverse to quality shall be analyzed to determine if it represents a significant condition adverse to quality. If so, then corrective action is required. The actions chosen and implemented are those most likely to eliminate the problem and to prevent recurrence.
- 22.3.4 The degree of corrective actions taken shall be appropriate to the magnitude and risk of the identified problem. Changes resulting from implementation of corrective actions shall be documented as quality records.
- 22.3.5 Procedures shall exist that require the monitoring of the corrective actions taken in order to ensure their effectiveness.
- 22.3.6 Any identified problems that indicate potentially serious quality program failures in the area identified shall result in that area being subjected to an internal audit as soon as possible.

**ATTACHMENT A
(Informative)**

Nominal Cross-References to ISO/IEC 17025 2005

4 Management Requirements

4.1 Organization

- 4.1.1 Section 1, paragraph 1
- 4.1.2 Section 1, paragraph 2 and 3, section 4.3.2
- 4.1.3 Section 1, paragraph 5
- 4.1.4 Section 2
- 4.1.5.a Section 2.3 paragraphs 1 and 2
- 4.1.5.b Section 2.3 1st paragraph
- 4.1.5.c Sections 9.3.4 and 9.3.5
- 4.1.5.d Section 1.1
- 4.1.5.e Section 2.4
- 4.1.5.f Section 2.3
- 4.1.5.g Section 4.6
- 4.1.5.h Section 2.3
- 4.1.5.i Section 2.3
- 4.1.5.j Section 2.3

4.2 Quality System

- 4.2.1 Section 1.1 and section 4
- 4.2.2.a Section 1.1
- 4.2.2.b Section 1.1
- 4.2.2.c Section 1.1
- 4.2.2.d Section 1.1
- 4.2.2.e Section 1.1
- 4.2.3 Section 1, paragraph 4
- 4.2.4 Section 2.3

4.3 Document Control

- 4.3.1 Section 5
- 4.3.2.1 Sections 5.4.1
- 4.3.2.2.a Section 5.4
- 4.3.2.2.b Section 5.4
- 4.3.2.2.c Section 5.4
- 4.3.2.2.d Section 5.4
- 4.3.2.3 Section 5.4.6
- 4.3.3.1 Section 5.5
- 4.3.3.2 Section 5.5
- 4.3.3.3 Not Applicable
- 4.3.3.4 Section 5.5

4.4 Review of Requests, Tenders and Contracts

- 4.4.1 Section 8.3
- 4.4.2 Section 8.4
- 4.4.3 Section 8.3.1
- 4.4.4 Section 8.5
- 4.4.5 Section 8.5

- 4.5 Subcontracting of Calibrations**
 - 4.5.1 Section 8.6
 - 4.5.2 Section 8.6
 - 4.5.3 Section 8.6
 - 4.5.4 Section 8.6

- 4.6 Purchasing Services and Supplies**
 - 4.6.1 Section 10
 - 4.6.2 Section 10
 - 4.6.3 Section 10
 - 4.6.4 Section 10

- 4.7 Service to the Client** Section 9.3

- 4.8 Complaints** Section 9.4

- 4.9 Control of Nonconforming testing and/or Calibration Work**
 - 4.9.1. Section 15.3
 - 4.9.2 Section 15.3

- 4.10 Corrective Action**
 - 4.10.1 Section 22
 - 4.10.2 Section 22.3.2
 - 4.10.3 Section 22.3
 - 4.10.4 Section 22.3.5
 - 4.10.5 Section 22.3.6

- 4.11 Preventive Action**
 - 4.11.1 Section 4.4
 - 4.11.2 Section 4.4

- 4.12 Control of Records**
 - 4.12.1.1 Section 6.1
 - 4.12.1.2 Section 6.3.3, 6.3.4, 6.3.5
 - 4.12.1.3 Section 6.3.6
 - 4.12.1.4 Section 6.3.7
 - 4.12.2.1 Section 6.4
 - 4.12.2.2 Section 6.4.6
 - 4.12.2.3 Section 6.4.7, 6.4.8

- 4.13 Internal Audits**
 - 4.13.1 Section 18.5, 18.5.1, 18.5.2, 18.5.3
 - 4.13.2 Section 18.5.4, 18.5.5

4.13.3	Section 18.5.6
4.13.4	Section 18.5.7
4.14	Management Review
4.14.1	Section 18.6.1 and 18.6.2
4.14.2	Section 18.6.3
5.0	Technical Requirements
5.1	General
5.1.1	Section 16.4
5.1.2	Section 14.3
5.2	Personnel
5.2.1	Section 4.5
5.2.2	Section 4.5
5.2.3	Section 4.5
5.2.4	Section 4.5
5.2.5	Section 4.5
5.3	Accommodation and Environmental Conditions
5.3.1	Section 16.5
5.3.2	Section 16.5
5.3.3	Section 16.5
5.3.4	Section 16.5
5.3.5	Section 16.5
5.4	Test and Calibration Methods and Method Validation
5.4.1	Section 11.3
5.4.2	Section 11.3
5.4.3	Section 11.3
5.4.4	Section 11.3
5.4.5.1	Section 11.3
5.4.5.2	Section 11.3
5.4.5.3	Section 11.3
5.4.6.1	Section 11.3
5.4.6.2	Section 11.3
5.4.6.3	Section 11.3
5.4.7.1	Section 11.3
5.4.7.2	Section 11.3
5.5	Equipment
5.5.1	Section 14.3
5.5.2	Section 14.3
5.5.3	Section 14.3
5.5.4	Section 14.3
5.5.5	Section 14.3
5.5.6	Section 14.3

5.5.7	Section 14.3
5.5.8	Section 14.3
5.5.9	Section 14.3
5.5.10	Section 14.3
5.5.11	Section 14.3
5.5.12	Section 14.3
5.6	Measurement Traceability
5.6.1	Section 14.4
5.6.2.1.1	Section 14.4
5.6.2.1.2	Section 14.4
5.6.3.1	Section 14.4
5.6.3.2	Section 14.4
5.6.3.3	Section 14.4
5.6.3.4	Section 14.4
5.7	Sampling
5.7.1	Section 16.4
5.7.2	Section 16.4
5.7.3	Section 16.4
5.8	Handling of Calibration Items
5.8.1	Section 17.5
5.8.2	Section 17.5
5.8.3	Section 17.5
5.8.4	Section 17.5
5.9	Calibration Results
	Section 16.7
5.10	Reporting of Calibration Results
5.10.1	Section 16.8
5.10.2	Section 16.8
5.10.3	Section 16.8
5.10.3.1	Section 16.8
5.10.3.2	Section 16.8
5.10.4	Section 16.8
5.10.4.1	Section 16.8
5.10.4.2	Section 16.8
5.10.4.3	Section 16.8
5.10.4.4	Section 16.8
5.10.5	Section 16.8
5.10.6	Section 16.8
5.10.7	Section 16.8
5.10.8	Section 16.8
5.10.9	Section 16.8

**ATTACHMENT B
(informative)**

Nominal Cross-References to ISO 9001:1994 and ISO 9002:1994

ISO 9001:1994	ISO 9002: 1994	ISO/IEC 17025
Clause 1	Clause 1	Clause 1
Clause 2	Clause 2	Clause 2
Clause 3	Clause 3	Clause 3
4.1.1	4.1.1	4.1.3, 4.2.2
4.1.2.1	4.1.2.1	4.1.5 a), f), h); 4.2.4; 4.9.1 a); 4.10.1 and 5.2.5
4.1.2.2	4.1.2.2	4.1.5 a), g), h) and 5.5.1
4.1.2.3	4.1.2.3	4.1.5 i)
4.1.3	4.1.3	4.14
4.2.1 and 4.2.2	4.2.1 and 4.2.2	4.2.1, 4.2.2, 4.2.3
4.2.3	4.2.3	4.2.1, 4.2.2 and 4.14
4.3	4.3	4.4
4.4	4.4 (n.a.)	1.5, 5.4.2, 5.4.3, 5.4.4, 5.4.5
4.5	4.5	4.3, 5.4.7, 5.5.11
4.6.1	4.6.1	4.6, 5.5, 5.6.1, 5.6.2.1, 5.6.2.2
4.6.2	4.6.2	4.5, 4.6
4.6.3	4.6.3	4.6
4.6.4	4.6.4	4.5, 4.6.4, 4.7, 5.5.2
4.7	4.7	5.8, 5.10.6
4.8	4.8	5.5.4, 5.8
4.9	4.9	4.12, 5.3, 5.4, 5.5, 5.8, 5.9
4.10.1	4.10.1	5.4
4.10.2	4.10.2	4.5, 4.6, 5.5.2, 5.8
4.10.3	4.10.3	4.9, 5.5.9, 5.8.3, 5.8.4, 5.9
4.10.4	4.10.4	5.4.7, 5.9, 5.10.1
4.10.5	4.10.5	4.12.2
4.11.1	4.11.1	5.4, 5.5, 5.6
4.11.2	4.11.2	5.3, 5.4.1, 5.4.5, 5.5, 5.6
4.12	4.12	5.5.12, 5.8, 5.9.2
4.13	4.13	4.9
4.14	4.14.1	4.10 and 4.11
4.15	4.15	5.9
4.16	4.16	4.12
4.17	4.17	4.10.5, 4.13 (4.12)
4.18	4.18	5.2, 5.5.3
4.19	4.19	4.7, 5.2.1, 5.10.5
4.20	4.20	5.9
n.a. = not applicable		

ISO/IEC 17025 covers several technical competence requirements that are not covered by ISO 9001:1994 and ISO 9002:1994